

103
**REVIEW OF THE REGISTRATION AND REREGISTRATION PROCESS
OF THE ENVIRONMENTAL PROTECTION AGENCY UNDER THE
FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT**

Y 4. AG 8/1:103-20

Review of the Registration and Rere...

HEARINGS

BEFORE THE

**SUBCOMMITTEE ON DEPARTMENT OPERATIONS
AND NUTRITION**

OF THE

**COMMITTEE ON AGRICULTURE
HOUSE OF REPRESENTATIVES**

ONE HUNDRED THIRD CONGRESS

FIRST SESSION

JUNE 8, 10, AND JULY 14, 1993

Serial No. 103-20



**SUPERINTENDENT OF DOCUMENTS
DEPARTMENT**

MAR 16 1994

**BOSTON PUBLIC LIBRARY
ACQUISITION DEPARTMENT**

Printed for the use of the Committee on Agriculture

**REVIEW OF THE REGISTRATION AND REREGISTRATION PROCESS
OF THE ENVIRONMENTAL PROTECTION AGENCY UNDER THE
FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT**

HEARINGS

BEFORE THE

**SUBCOMMITTEE ON DEPARTMENT OPERATIONS
AND NUTRITION**

OF THE

**COMMITTEE ON AGRICULTURE
HOUSE OF REPRESENTATIVES**

ONE HUNDRED THIRD CONGRESS

FIRST SESSION

JUNE 8, 10, AND JULY 14, 1993

Serial No. 103-20



Printed for the use of the Committee on Agriculture

U.S. GOVERNMENT PRINTING OFFICE

71-926

WASHINGTON : 1994

For sale by the U.S. Government Printing Office
Superintendent of Documents, Congressional Sales Office, Washington, DC 20402

ISBN 0-16-043470-X

COMMITTEE ON AGRICULTURE

E (KIKI) DE LA GARZA, Texas, *Chairman*

GEORGE E. BROWN, JR., California,
Vice Chairman

CHARLIE ROSE, North Carolina
GLENN ENGLISH, Oklahoma
DAN GLICKMAN, Kansas
CHARLES W. STENHOLM, Texas
HAROLD L. VOLKMER, Missouri
TIMOTHY J. PENNY, Minnesota
TIM JOHNSON, South Dakota
BILL SARPALIUS, Texas
JILL L. LONG, Indiana
GARY A. CONDIT, California
COLLIN C. PETERSON, Minnesota
CALVIN M. DOOLEY, California
EVA M. CLAYTON, North Carolina
DAVID MINGE, Minnesota
EARL F. HILLIARD, Alabama
JAY INSLEE, Washington
THOMAS J. BARLOW III, Kentucky
EARL POMEROY, North Dakota
TIM HOLDEN, Pennsylvania
CYNTHIA A. MCKINNEY, Georgia
SCOTTY BAESLER, Kentucky
KAREN L. THURMAN, Florida
SANFORD D. BISHOP, JR., Georgia
BENNIE G. THOMPSON, Mississippi
SAM FARR, California
PAT WILLIAMS, Montana
BLANCHE M. LAMBERT, Arkansas

PAT ROBERTS, Kansas,
Ranking Minority Member
BILL EMERSON, Missouri
STEVE GUNDERSON, Wisconsin
TOM LEWIS, Florida
ROBERT F. (BOB) SMITH, Oregon
LARRY COMBEST, Texas
WAYNE ALLARD, Colorado
BILL BARRETT, Nebraska
JIM NUSSLE, Iowa
JOHN A. BOEHNER, Ohio
THOMAS W. EWING, Illinois
JOHN T. DOOLITTLE, California
JACK KINGSTON, Georgia
BOB GOODLATTE, Virginia
JAY DICKEY, Arkansas
RICHARD W. POMBO, California
CHARLES T. CANADY, Florida
NICK SMITH, Michigan
TERRY EVERETT, Alabama

PROFESSIONAL STAFF

DIANNE POWELL, *Staff Director*
VERNIE HUBERT, *Chief Counsel and Legislative Director*
GARY R. MITCHELL, *Minority Staff Director*
JAMES A. DAVIS, *Press Secretary*

SUBCOMMITTEE ON DEPARTMENT OPERATIONS AND NUTRITION

CHARLES W. STENHOLM, Texas, *Chairman*

GEORGE E. BROWN, JR., California,
Vice Chairman
BILL SARPALIUS, Texas
CALVIN M. DOOLEY, California
JAY INSLEE, Washington
GLENN ENGLISH, Oklahoma
DAN GLICKMAN, Kansas
CYNTHIA A. MCKINNEY, Georgia
SANFORD D. BISHOP, JR., Georgia
HAROLD L. VOLKMER, Missouri
EVA M. CLAYTON, North Carolina
TIM HOLDEN, Pennsylvania
CHARLIE ROSE, North Carolina
SAM FARR, California
TIM JOHNSON, South Dakota
EARL POMEROY, North Dakota
BLANCHE M. LAMBERT, Arkansas

ROBERT F. (BOB) SMITH, Oregon
BILL EMERSON, Missouri
STEVE GUNDERSON, Wisconsin
WAYNE ALLARD, Colorado
BILL BARRETT, Nebraska
JOHN A. BOEHNER, Ohio
THOMAS W. EWING, Illinois
JACK KINGSTON, Georgia
CHARLES T. CANADY, Florida

CONTENTS

JUNE 8, 1993

	Page
Canady, Hon. Charles T., a Representative in Congress from the State of Florida, prepared statement	13
Clayton, Hon. Eva M., a Representative in Congress from the State of North Carolina, prepared statement	9
de la Garza, Hon. E (Kika), a Representative in Congress from the State of Texas, remarks of	65
Roberts, Hon. Pat, a Representative in Congress from the State of Kansas, prepared statement	3
Smith, Hon. Robert F. (Bob), a Representative in Congress from the State of Oregon, prepared statement	6
Stenholm, Hon. Charles W., a Representative in Congress from the State of Texas, opening statement	1

WITNESSES

Balek, William C., director, legislative affairs, International Sanitary Supply Association	48
Prepared statement	219
Engel, Ralph, president, Chemical Specialties Manufacturers Association	41
Prepared statement	172
Feldman, Jay, executive director, National Coalition Against the Misuse of Pesticides	18
Prepared statement	128
Gullickson, William, chairman, Chemical Producers & Distributors Association	44
Prepared statement	194
Hinkle, Maureen Kuwano, director, agricultural policy, National Audubon Society	14
Prepared statement	95
Kimm, Victor J., Acting Assistant Administrator, Office of Prevention, Pesticides, and Toxic Substances, U.S. Environmental Protection Agency	61
Prepared statement	240
Response to written questions from Mr. Roberts	270
Olson, Erik D., senior attorney, Natural Resources Defense Council	16
Prepared statement	101
Pflug, Gerald R., president, Soap & Detergent Association	47
Prepared statement	216
Rominger, Richard, Deputy Secretary, U.S. Department of Agriculture	58
Prepared statement	232
Wiles, Richard, director, agricultural pollution prevention project, Center for Resource Economics	21
Prepared statement	151
Vroom, Jay, president, National Agricultural Chemicals Association	39
Prepared statement	155

SUBMITTED MATERIAL

Averbach, Steven, analyst, food and agriculture policy, U.S. Chamber of Commerce, statement	282
Gray Panthers, statement	287

IV

JUNE 10, 1993

	Page
Dooley, Hon. Calvin M., a Representative in Congress from the State of California, opening statement	290
Gunderson, Hon. Steve, a Representative in Congress from the State of Wisconsin, opening statement	291
Smith, Hon. Robert F. (Bob), a Representative in Congress from the State of Oregon, opening statement	290
Stenholm, Hon. Charles W., a Representative in Congress from the State of Texas, opening statement	289

WITNESSES

Botts, Daniel A., chairman, technical committee, Minor Crop Farmer Alliance, and director, environmental and pest management division, Florida Fruit & Vegetable Association	297
Prepared statement	353
Brown, Arthur R., Jr., secretary of agriculture, New Jersey Department of Agriculture	292
Prepared statement	338
Caulder, Jerry, president and chief executive officer, Mycogen Corp	324
Prepared statement	422
Davis, James H., vice president, research and development, Crop Genetics International Corp., on behalf of the Industrial Biotechnology Association ..	323
Prepared statement	416
Guest, Richard T., national director, Interregional Research Project No. 4, Rutgers University	294
Prepared statement	344
Hazeltine, William, on behalf of the American Mosquito Control Association ..	301
Prepared statement	368
Letter of June 29, 1993	307
Maslyn, Mark, vice chairman, Minor Crop Farmer Alliance, and director, governmental affairs, American Farm Bureau Federation	296
Prepared statement	353
Templeton, George E., distinguished professor, department of plant pathology, college of agriculture and home economics, University of Arkansas	318
Prepared statement	392
Wylie, James A., Jr., president and chief executive officer, EcoScience Corp ...	320
Prepared statement	407

JULY 14, 1993

Clayton, Hon. Eva M., a Representative in Congress from the State of North Carolina, prepared statement	451
Lambert, Hon. Blanche M., a Representative in Congress from the State of Arkansas, prepared statement	453
Roberts, Hon. Pat, a Representative in Congress from the State of Kansas, prepared statement	454
Smith, Hon. Robert F. (Bob), a Representative in Congress from the State of Oregon, prepared statement	456
Stenholm, Hon. Charles W., a Representative in Congress from the State of Texas, opening statement	429

WITNESSES

Gianessi, Leonard P., fellow, Resources for the Future	471
Prepared statement	523
Graham, John D., director, Center for Risk Analysis, Harvard University School of Public Health	466
Prepared statement	497
Mattison, Donald R., M.D., professor, environmental and occupational health and obstetrics and gynecology; dean, graduate school of public health, University of Pittsburgh; and vice chairman, committee on pesticides in the diets of infants and children, National Research Council	432
Prepared statement	486
Reigart, J. Routt, M.D., chairperson, committee on environmental health, American Academy of Pediatrics	430
Prepared statement	482

Seiber, James N., director, center for environmental sciences and engineering, University of Nevada, and member, committee on pesticides in the diets of infants and children, National Research Council	436
Prepared statement	493
Winter, Carl K., extension food toxicologist, University of California-Davis	469
Prepared statement	505

REVIEW OF THE REGISTRATION AND REREGISTRATION PROCESS OF THE ENVIRONMENTAL PROTECTION AGENCY UNDER THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

TUESDAY, JUNE 8, 1969

HOUSE OF REPRESENTATIVES SUBCOMMITTEE ON DEPARTMENT OPERATIONS AND NUTRITION, COMMITTEE ON AGRICULTURE WASHINGTON, D.C.

The subcommittee met, pursuant to call, at 10:05 a.m. in room 1300, Longworth House Office Building. Hon. Charles W. Stenholm, chairman of the subcommittee, presiding.

Present: Representatives Dwyer, English, Glickman, Holden, Lambert, South, Gundersen, Allard, Ewing, and Canady.

Also present: Representative E. (Klax) DeLoe, chairman of the committee.

Staff present: William E. O'Connor, Jr., minority policy coordinator; John E. Hagan, minority counsel; Dale Moore, minority legislative coordinator; Gladys L. Thomas, clerk; Paul Ray, Nick Wilson, James A. Davis, Curt Mann, and two visitors.

OPENING STATEMENT OF HON. CHARLES W. STENHOLM, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. STENHOLM: This hearing will come in order.

This morning we begin to focus the subcommittee's attention on the pesticide registration and reregistration process. This issue is only one piece of a larger and very complex puzzle out, nevertheless, one that is broad enough to bring a wide and diverse group of interests to the table in our attempt to identify legislative concerns and begin a sincere and diligent effort to address them.

This morning—and I would venture to say most of our subcommittee—supports the use of pesticides. That is, I do not categorically reject them, as some might advocate. We use them not only on our Nation's farms and throughout our food production systems but in our homes and everyday lives. Pesticides, and other technologies, serve a tremendous benefit to society which many of us take for granted or choose to overlook.

With that said, and as a farmer in real life, I want want to use any new pesticides, herbicides, or any other technology that I have to. First of all, the stuff is terribly expensive. But most important of all, I want to think and argue that the pesticides I do use,

REVIEW OF THE REGISTRATION AND REREGISTRATION PROCESS OF THE ENVIRONMENTAL PROTECTION AGENCY UNDER THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

TUESDAY, JUNE 8, 1993

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON DEPARTMENT
OPERATIONS AND NUTRITION,
COMMITTEE ON AGRICULTURE,
Washington, DC.

The subcommittee met, pursuant to call, at 10:05 a.m., in room 1300, Longworth House Office Building, Hon. Charles W. Stenholm (chairman of the subcommittee) presiding.

Present: Representatives Dooley, English, Glickman, Holden, Lambert, Smith, Gunderson, Allard, Ewing, and Canady.

Also present: Representative E (Kika) de la Garza, chairman of the committee.

Staff present: William E. O'Conner, Jr., minority policy coordinator; John E. Hogan, minority counsel; Dale Moore, minority legislative coordinator; Glenda L. Temple, clerk; Stan Ray, Rob Wight, James A. Davis, Curt Mann, and Pete Thomson.

OPENING STATEMENT OF HON. CHARLES W. STENHOLM, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. STENHOLM. This hearing will come to order.

This morning we begin to focus the subcommittee's attention on the pesticide registration and reregistration processes. This issue is only one piece of a larger and very complex puzzle but, nevertheless, one that is broad enough to bring a wide and diverse group of interests to the table in our attempt to identify legitimate concerns and begin a sincere and diligent effort to address them.

This member—and I would venture to say most of this subcommittee—supports the use of pesticides. That is, I do not categorically reject them, as some might advocate. We use them not only on our Nation's farms and throughout our food production systems but in our homes and everyday lives. Pesticides, and other technologies, serve a tremendous benefit to society which many of us take for granted or choose to overlook.

With that said, and as a farmer in real life, I don't want to use any more pesticides, herbicides, or any other technology than I have to. First of all, the stuff is terribly expensive. But most important of all, I want to trust and expect that the pesticides I do use,

in accordance with the label, are scientifically proven to be effective without creating unnecessary risks to myself, my family, my neighbors, and the rest of society.

If there are effective and appropriate alternatives, let's talk about them. If the system has created special problems for certain products and uses, let's talk about that. If efficiencies can be made in the current process or if the foundation upon which the whole process is based can be improved, let's take a look at that. Whatever the issues are, let's talk about them and get about the business of taking care of our business.

The status quo has got to change. The American public does not trust this institution or its agencies to do what's in their best interest. If we are sincere in maintaining, and in most cases, regaining public confidence in our Nation's pesticide policy, we cannot continue down the path of divisiveness, confrontation, and dissension. The public's tolerance is growing thin. We must be willing to look at everything on the table and consider creative and innovative options if we expect to responsibly address what I believe to be some very legitimate concerns.

With that, I look forward to all of your testimony today and thank you for helping this subcommittee understand these complex and seemingly controversial issues so that we can begin the work of making necessary improvements.

And I emphasize, this hearing today is the beginning of what we believe will be a very lengthy but also a very productive endeavor this year as we bring about a successful culmination to the issues which we begin today.

Mr. Smith.

Mr. SMITH. Thank you, Mr. Chairman. I have a statement for the record, as well as Congressman Roberts.

Mr. STENHOLM. Without objection, both statements will be made a part of the record.

[The prepared statements of Mr. Roberts and Mr. Smith follow:]

The Honorable Pat Roberts
Hearing Statement before the
Department Operations and Nutrition Subcommittee
RE: Review of FIFRA registration and reregistration provisions
June 8, 1993

Thank you Mr. Stenholm and Mr. Smith for calling today's hearing. I look forward to your leadership on one of my favorite issues: The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Since the early 1970's when the federal laws and regulations governing pesticides were shifted from a primary focus on the efficacy of products to one based on human health and environmental concerns, Congress, the Administration, the chemical industry, and the environmental community have battled over balancing the recognized risks pesticides their use may pose and the benefits they can provide.

Throughout these battles, it has been a challenge to ensure those industries and public institutions -- such as farms, food processing operations, hospitals, etc. -- that use pesticide products are recognized as full partners in the efforts to update and reform FIFRA. I know this Subcommittee will make certain common sense and valid science are the guide posts used to develop rational legislative proposals where they are needed.

I commend you for holding the first FIFRA hearing of the 103rd Congress on registration and reregistration provisions. Over the past four years, the FIFRA and Federal Food, Drug, and Cosmetic Act (FFDCA) debates have focused primarily on the Delaney clause, streamlining cancellation and suspension provisions, and increasing the use restrictions and/or monitoring the use of pest control products.

But since the major revision of FIFRA in 1988 to tackle the reregistration of active ingredients and products registered before 1985, there has not been much time or attention devoted to the increasingly difficult process of registering new products. Certainly, the improved and expanded testing required for new and old products helps ensure there is sufficient data to make accurate, scientific judgements on the safety of pesticide products.

However, the combination of higher registration hurdles and as the fiscal and resource impact of efforts to move the 400-plus remaining "old" active ingredients through reregistration have led -- to use a tired phrase -- to gridlock.

That is why I am encouraged that the Subcommittee has chosen to begin this session's FIFRA oversight on the provisions governing pesticide registration. This oversight is critical for a couple of reasons. First, it must be determined where FIFRA needs to be strengthened. While there may be shortcomings in the law, part of FIFRA's strength is that it does provide the EPA Administrator with a lot of flexible authority to meet the challenges of regulating pesticide use.

Roberts, FIFRA Hearing, page two

Unfortunately, the Agency often appears reluctant to use its administrative flexibility to resolve conflicts, preferring, it seems, to force contentious debate in Congress and the private sector.

I do recognize that resources -- both public and private -- also are part of the problem. In order for a company to bring new products to market that may pose reduced risks to human health, the environment, or to those using their products, the process of registering these new products must be rational, timely and affordable.
Roberts, 6-8-93

Some of this can be achieved by encouraging the federal and state agencies that play a role in regulating pesticide development, manufacture and use to coordinate their testing and data submission requirements whenever possible. Additional progress may be made through the cooperative efforts of regulators, agriculture and chemical industries, and the environmental community to lobby for appropriations that would alleviate some of the projected shortfall in EPA's reregistration costs -- certainly a tall order in these days of tight budgets.

But most important, we need the EPA to aggressively use its administrative authority to adjust, massage, and simply fix the problems and conflicts that pop up. The practice of leaving it up to Congress simply continues the debate, which with each passing Congress brings new issues to the table with the old ones seldom being resolved.

There are some specific concerns that need to be examined.

For example, we have heard in previous FIFRA hearings that the reregistration process is suffering from funding shortfalls. EPA testified in the last session that reregistration fee collections were running about \$3 million short of the \$14 million projected in the analysis of the 1988 FIFRA amendments, due in part to the economic realities confronting registrants relative to the costs of tests to provide EPA the data requested on any given product.

Also during last session, when this Subcommittee was working on a FIFRA reform package, it was suggested that to make up this shortfall, we should authorize a broader, more permanent fee structure. This was on top of fee structure provisions changed in the 1990 farm bill technical corrections package.

All of which reminds me of questions raised in the past that have proven difficult to get answered:

-- Can EPA provide an accounting of the reregistration fees collected? There have been charges and speculation that reregistration fees have been used for purposes not authorized. While I do not subscribe to this theory, a detailed accounting would help clear up this question.

Roberts, FIFRA Hearing, page three

- Does EPA have the ability, when conducting such an accounting, to provide the number and total amount of the fees collected, and how they have been spent in support of maintaining the timetable specified to meet the 1997 deadline -- a deadline most agree will not be met?
- We have received analyses in the past detailing the funding shortfall caused by the lower-than-expected fee collections. Has EPA kept detailed records on the appropriations shortfalls that have contributed to these projections -- particularly with respect to the projections made during passage of FIFRA-88?

Second, there is a troubling aspect to the provisions of the 1990 farm bill relative to pesticide record keeping. Recently, we received a letter from today's EPA witness, Mr. Victor Kimm, stating that because of "recent reduction in our [EPA's] fiscal year 1993 budget . . . we are not in a position to conduct even a limited sampling survey of certified applicators in 1993."

I am concerned that although the farm bill is clear in its mandate by stating in Title 14, Section 1491(f), that the "Secretary of Agriculture and the Administrator of the [EPA], shall [emphasis added] survey the records maintained under subsection (a) to develop and maintain a data base that insufficient to enable the Secretary and the Administrator to publish annual comprehensive reports concerning agricultural and nonagricultural pesticide use. . .," Mr. Kimm's letter indicates the Agency has determined it cannot, or will not, follow the mandates of the law. I believe the Secretary of Agriculture has or is working to meet his responsibilities to this provisions.

Obviously, I am concerned that a mandated provision of law will not be fulfilled, and I encourage this Subcommittee to discover how this mandate has been set aside for this fiscal year. In addition, this same provision requires the USDA and the EPA to develop and implement a "memorandum of understanding" relative to the Secretary and Administrator's responsibilities in meeting the requirements of the farm bill's recordkeeping provisions. This should be made part of the record.

To quote Chairman de la Garza, politics is the art of the possible. When critical pieces of the puzzle are missing -- particular relative to pesticides and food safety -- the art of developing meaningful pesticide policy reforms quickly becomes impossible.

STATEMENT OF ROBERT F. SMITH
BEFORE THE
SUBCOMMITTEE ON DEPARTMENT OPERATIONS & NUTRITION
JUNE 8, 1992

I'd like to commend the Chairman for beginning this year's hearing on agricultural chemical issues with an examination of registration and reregistration.

The many problems currently faced by this nation's agriculture community, with respect to chemical use, tend to cluster around two subjects: the Delaney Clause of the Federal Food, Drug and Cosmetic Act (FFDCA) and registration/reregistration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

Minor use, so-called "reduced risk" products, questions about fee revenue and even the very nature of the pesticide regulatory process, all begin with registration and reregistration.

I am convinced that if these issues can be resolved to everyone's satisfaction, then much of the FIFRA debate could be put behind us. It makes sense to start here because we will eventually return here.

Another observation I would like to offer today is that the successful evolution of sound federal policy will depend, in larger part on the roles played by each of us in the debate.

Congress has wrestled with FIFRA issues on a constant basis for years. Numerous proposals are introduced, examined and refined during each Congress. Hearing and legislative records are long and detailed.

For us to go beyond this week's hearings, in order for us to make any substantive progress with future hearings, we need the President to complete his appointments and we need some indication regarding the Administration goals.

Seven of sixteen political positions have been filled at the Environmental Protection Agency; the Office of Prevention, Pesticides, and Toxic Substances is represented today by an Acting Administrator. And, to my knowledge, the Administration has yet to outline a policy or endorse any of the many current legislative options before Congress.

Public policy is a team sport. This Committee deserves to work with an Administration which can field a complete team. Not only do I want to know who's going to play, I want to know what game they want to play. We need some indication about the goals of the President's pesticide policy.

Finally, I'd like to talk about discretionary authority. This Committee has demonstrated time and again its confidence in the Executive Branch by incorporating considerable discretionary authority into our legislation.

I think I can speak for my colleagues in saying that we expect these authorities to be used to resolve, not create, crisis for our nation's farmers, ranchers and consumers.

If this proves not to be the case, we will find ourselves in the unfortunate situation of micromanaging the operation programs which should be based on science, not politics.

Mr. Chairman, I look forward to the testimony of today's, and thursday's, witnesses.

Mr. STENHOLM. Mr. Canady.

Mr. CANADY. Thank you, Mr. Chairman. I also have a statement for the record I would like to submit.

Mr. STENHOLM. Without objection. Any other prepared statements received from the members will be placed at this point in the record.

[The prepared statements of Mrs. Clayton and Mr. Canady follow:]

EVA M. CLAYTON
1ST DISTRICT, NORTH CAROLINA

HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-3301
(202) 225-3101

Congress of the United States
House of Representatives
Washington, DC 20515-3301

OPENING STATEMENT FOR REP. EVA CLAYTON
PESTICIDE HEARING--SUBCOMMITTEE ON
DEPT. OPERATIONS AND NUTRITION
8 JUNE 1993

THANK YOU MR. CHAIRMAN. I WOULD LIKE TO WELCOME THE PARTICIPANTS OF TODAY'S HEARING AND THANK THEM FOR THEIR USEFUL COMMENTS IN REGARDS TO THIS HIGHLY COMPLICATED ISSUE. THE REVISITATION OF THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT (FIFRA) WILL BE A HIGHLY CHARGED AND TEDIOUS DEBATE. HOWEVER, IF WE ARE TO PROVIDE FOR AN EFFICIENT SYSTEM THAT PROVIDES FOR THE PUBLIC INTEREST, WE

MUST BE WILLING FACE MANY OF THESE PROBLEMS "HEAD ON."

AS A NEW MEMBER OF THE AGRICULTURE COMMITTEE, I HAVE BEEN BOMBARDED WITH A VARIETY OF ISSUES WHICH INVOLVE WALKING THE PRECARIOUS TIGHTROPE BETWEEN ENVIRONMENTAL CONCERNS AND ECONOMIC INTEREST. I AM ONE THAT BELIEVES THAT THE TWO ARE NOT MUTUALLY EXCLUSIVE. HOWEVER, WE MUST WORK DILIGENTLY TO ACHIEVE THE OPTIMUM BALANCE IN ORDER TO SECURE THE INTEREST OF THE TOTAL AGRICULTURE COMMUNITY. I LIKE TO REMIND MY COLLEAGUES AND PEERS THAT FARMERS WERE THE FIRST ENVIRONMENTALISTS! WITHOUT VIABLE LAND—THERE WOULD BE NO FARMER.

HOWEVER, THERE ARE A NUMBER OF ISSUES

THAT CONCERN ME. IS THERE A PREPONDERANT RISK TO CHILDREN FROM THE INGESTION OF PESTICIDE RESIDUES? CAN WE DEFINE ACCEPTABLE RISK AND CREATE AND IMPLEMENT WORKING STANDARDS FOR PESTICIDES? TO SOME EXTENT I HAVE HEARD MIXED SIGNALS FROM ACADEMIC FINDINGS AND THE INTERESTED PARTIES. FURTHERMORE, HOW CAN WE RESOLVE THE SO-CALLED "DELANEY PARADOX" IN ORDER TO SUFFICIENTLY SATISFY THE NEEDS OF PUBLIC HEALTH AND THE CONCERNS OF INDUSTRY.

I AM HOPEFUL THAT THIS SERIES OF HEARINGS WILL SERVE TO SHED LIGHT ON THESE ISSUES AND EDUCATE THOSE OF US WHO WILL BE SHAPING POLICY. AGAIN, I WOULD LIKE TO WELCOME THE PANELISTS AND EXTEND TO THE CHAIRMAN MY GRATITUDE FOR

**FOCUSING THE SUBCOMMITTEE'S ATTENTION ON
THIS CRUCIAL SUBJECT MATTER.**

THANK YOU.

CHARLES T. CANADY
12TH DISTRICT, FLORIDA

COMMITTEE ON AGRICULTURE
DEPARTMENT OPERATIONS AND NUTRITION
FOREIGN AGRICULTURE AND HUNGER

COMMITTEE ON THE JUDICIARY
CIVIL AND CONSTITUTIONAL RIGHTS
ECONOMIC AND COMMERCIAL LAW
INTERNATIONAL LAW, IMMIGRATION,
AND REFUGEES

1107 LONGWORTH BUILDING
WASHINGTON, DC 20515-0912
(202) 225-1252

FEDERAL BUILDING
124 SOUTH TENNESSEE AVENUE
LAKELAND, FL 33801
(813) 688-2651

Congress of the United States
House of Representatives
Washington, DC 20515-0912

THE HONORABLE CHARLES T. CANADY
of Florida

before the House Agriculture Subcommittee on
Department Operations and Nutrition

June 8, 1993

MR. CHAIRMAN, I want to commend you and Mr. Smith for convening this hearing to review the federal process by which pesticides and agricultural chemicals are registered and reregistered.

Given its sub-tropical growing conditions, Florida's \$6.1 billion agriculture industry relies on the availability of up-to-date, effective agricultural chemicals and pesticides to battle pests and infestations. Unfortunately, because of pressures to restrict and sometimes eliminate the use of pesticides and chemicals, coupled with the time needed to research, develop and register new active ingredients, Florida's agriculture industry has found that the list of available pesticides is rapidly diminishing.

The increased maintenance and testing fees have played a major role in the loss of several thousand pesticide registrations. Many agriculture chemical producers have voluntarily dropped registrations because of these increased costs. This decline in registrations has greatly impacted Florida's fruit and vegetable industry.

Mr. Chairman, the issue before us is a monumental one. Not only do America's farmers rely on us for an outcome that will allow them to continue their livelihood, but also, the American consumer relies on us to provide an outcome that will allow America's farmers to produce a safe, abundant food supply at a reasonable price.

Mr. Chairman, I look forward to working with the members of this committee, the representatives testifying here today and the American agriculture industry in order to develop a more effective and more efficient process for registering and reregistering pesticides. Thank you.

Mr. STENHOLM. We will call the first panel, Mrs. Maureen Hinkle, Mr. Erik Olson, Mr. Jay Feldman, Mr. Richard Wiles.

Mr. Dooley, any opening statement that you might have?

Mr. DOOLEY. No. I have no statement, Mr. Chairman.

Mr. STENHOLM. Without objection, each of your entire statements will be made a part of the record. We will appreciate it if you could hold your statements to 10 minutes.

We will give you an extra bonus of 5 minutes today. This is a very serious subject.

And we will recognize first Ms. Maureen Kuwano Hinkle, director, agricultural policy, National Audubon Society.

Welcome.

**STATEMENT OF MAUREEN KUWANO HINKLE, DIRECTOR,
AGRICULTURAL POLICY, NATIONAL AUDUBON SOCIETY**

Ms. HINKLE. Thank you, Mr. Chairman.

This is the first time I have ever been first, and I don't know how this happened; but I am very grateful.

As some of you know, I have been involved in pesticides for 20 years. The last 12 years I have been with the National Audubon Society, and before that I was with the Environmental Defense Fund.

Back in 1972, there were only three environmental groups that were involved in pesticides. And today there are several dozen. In all this time, FIFRA has only been amended twice in 1978 to open up trade secrets and in 1988 to accelerate reregistration. However, today, as EPA prepare to become a full Cabinet member, there is this unparalleled opportunity to amend FIFRA in a significant way.

The preoccupation with pesticides has been with chemicals, and there are several reasons for that which I go into in my statement. But today there is a need for alternatives that we should put as a high priority because of two prominent problems. The first is resistance.

Since the DDT case of resistance, insects as a group have never met a chemical they couldn't take to the mat. Another way of putting this problem is that resistance is removing chemicals faster than EPA can regulate them. Growers need alternative pest controls.

The second problem is exotic pests. Because of the increasing global traffic, there are more pests that are entering this country than we have controls for them. We need not only available means, but we need to go into a preventative mode to try to prepare for a more holistic way to take care of them.

Apart from the two prominent problems, removing the chemicals because of resistance and new pests, we have problems posed by existing chemicals to human health and the environment, including diminishing wildlife, ground and surface water contamination, and even ozone depletion. Growers and land managers need control agents that are less intrusive of the ecosystem into which they are released.

Audubon urges USDA to make a high priority for biological controls which require a considerable knowledge base, which we don't now have, and has never received the emphasis or the funding that it should have.

The problems with minor uses illustrates the problems that we have for biological controls, and that is the market is so small that it attracts very little commercial investment. Unless there is a significant increase in funding for research and development of alternatives and incentives provided for those who wish to pursue their commercialization, there will never be the variety and number of control agents needed by grower and land managers.

In the last session of Congress, Representative Charlie Rose sponsored a provision that would create incentives for new generation pesticides. I hope that you can build on the incentives that were contained in that section and provide for greater incentives for these controls.

We also believe that EPA should be required to organize and consolidate existing resources to form teams from all their divisions. These teams should function as a critical mass to accelerate the evaluation process for all nonconventional pesticides.

At the same time, USDA could launch a policy of instructing extension officials in strategies and tactics oriented toward reduced pesticide use and identification of natural controls existing in the areas where they work.

Minor-use legislation should not proceed without incentives for alternative control agents for all crops, including minor crops.

Audubon would also like EPA to define benefits in a different way than they have in the past. In the past, benefits were defined as increased yield per acre, per year. And although yields were frozen at the 1986 level, that level was extremely high and is not necessarily what should be the realistic yield goal for each acre. Instead of, for instance, annual set-aside percentages, realistic yield could serve as a more environmental production control device.

These realistic yield goals would be based on a limit to the realized yield benefits of increased applications of nitrogen and agricultural chemicals. In many areas, these limits have been found; and they do guide the use of these chemicals. But they are not factored into EPA's benefits analysis. After such limits have been empirically established, EPA could be required to define benefits according to established yield goals instead of increased yields per acre, per year as they have in the past.

Actual pesticide use data, in our view, is the best answer to a host of problems that have proven intractable over the past several decades. In the absence of actual pesticide use surveys, EPA applies a theoretical maximum tolerance level. With actual use data, EPA could use a scalpel for regulatory purposes instead of a sledge hammer. EPA could know what use patterns prevail on which crops and could then proceed to require use reductions where they are unnecessarily high or where they are sufficiently high to raise safety concerns.

So we have made recommendations for three changes in the current recordkeeping language.

Finally, we urge USDA and EPA to address resistance management strategies to prevent and delay resistance to existing chemicals as well as to new ones such as plants that are being manufactured to produce pest control agents.

We believe that enactment of such legislation would constitute a breakthrough for EPA that would benefit everyone—growers, envi-

ronmental groups, Government agencies, potential registrants, and the public at large. These proposals would bring the relevant agencies together to work out problems of mutual concern in new ways, and would add efficiency, purpose, and clarity to the regulatory process.

We would welcome working out the details, and we would like our energies to be dedicated toward raising FIFRA out of what has been called the doldrums.

[The prepared statement of Ms. Hinkle appears at the conclusion of the hearing.]

Mr. STENHOLM. Mr. Erik Olson, senior attorney, Natural Resources Defense Council.

STATEMENT OF ERIK D. OLSON, SENIOR ATTORNEY, NATURAL RESOURCES DEFENSE COUNCIL

Mr. OLSON. Thank you. I want to thank you and express our hope that we can work productively with this subcommittee and the full committee and the new chairman of DONUT, I guess they are calling it these days.

We are going to be presenting some more detailed proposals for reform. What I would like to do is simply summarize my statement rather than reading through it.

Basically, we think that FIFRA has had some successes, that there are notable examples where FIFRA has worked. The DDT example is one that many have cited, but unfortunately it has failed in many respects. It has failed to protect the farmers and provide predictable and timely reviews of chemicals. I think the environmental community understands that farmers don't want to use expensive chemicals that are potentially toxic and may contaminate wells and food. What they want is something that is effective and proven safe, and they want something that doesn't have resistant pests being developed. They want something they can rely on, in short.

I can tell you from my earliest memories that I know in the Midwest that farmers live a tough life, and they want to use something that is effective. They would prefer not to use something that is going to cause them problems, their family problems, or the environment problems. Unfortunately, FIFRA has failed to provide assurance that there are these effective alternatives available when a problem chemical comes along.

It also, unfortunately, has failed to protect farmworkers and has failed to protect the environment. What we now see is that surface waters are contaminated. One out of four of the samples taken in the Mississippi basin have been contaminated with atrazine at above the EPA limit. And 50 percent of the ground wells had pesticides in them. And fish in the Great Lakes continue to have significant levels of pesticides in them, even pesticides that were banned over 10 years ago. And there are subtle effects on the reproductive and endocrine systems of fish and wildlife.

Unfortunately, FIFRA has failed to produce consumer confidence that food is safe. In unison with that, FFDCA has failed to encourage a shift to less dangerous alternatives and use of both chemical and nonchemical alternatives that are safer than the ones in widespread use.

In large part, we rest much of the blame on FIFRA's cumbersome procedural requirements. I think it is worth remembering what former Administrator Reily said in a statement that he made several years ago—and I think it is worth quoting. He said: "The process is very complicated, duplicative, and inefficient. This country cancels trading in bad stock faster than it gets rid of a bad pesticide. We must address this issue by removing one of the very duplicative parts of the process, the adjudicatory hearing * * *"

He goes on to say: "Where we now have a 4- to 8-year process from start to finish for cancelation, we urge Congress to adopt reform legislation to reduce the period to something in the range of a couple of years. We have the authority to suspend a chemical under certain circumstances. But that power has only been exercised three times in EPA history. The standard for exercising it is very rigorous. The courts have, in fact, found that we proposed to exercise it inappropriately in the past and have prevented us from using this authority."

He also noted that he thinks it was an untenable situation. He said: "It's one that has long needed addressing. I think it's one of the strongest elements in this set of proposals that the administration then made."

He said: "That we remove the adjudicatory hearing, the de novo review, that has added so many years to that process, and I would expect that anybody who looks at that will recognize that this is going to make for a much stronger and more protective implementation of that law."

So we clearly believe, as did the past administration—and I believe this administration—that there is a need for reform of FIFRA. There is a need to improve, as well, we feel, the enforcement and registration and reregistration procedures. There is a need to encourage the adoption and the research into other alternatives to problem pesticides.

And we also believe that there is need for help on minor-use issues. That IR-4 and other programs need to be fully funded to assure that alternatives to the minor-use pesticides that may be canceled or overdeveloped—and that other data that needs to be developed for those uses—is brought into the public arena more quickly.

There is also an urgent need for better use data as Maureen Hinkle just suggested. The other reforms that I don't propose to talk about in any detail but are discussed in our written statement is the need for food safety reform. As the chairman knows, the Delaney clause has recently been interpreted by the U.S. court of appeals in California to say that pesticides that concentrate in processing and that cause cancer are banned from processed foods.

However, we believe that, as part of an overall package—although we are not unhappy with the Delaney clause—as it now stands, we believe that an overarching package of reforms in food, safety, and pesticide policy is something that we are ready to work with this subcommittee and the full committee with and the House Energy and Commerce Committee.

And we believe that, overall, we can reform pesticide policy in a way that we have been unable to do in the past 20 years. We have a unique opportunity. The opportunity for reform is crystallized. We have an administration that is interested in working on the issue,

and I believe that Congress is interested in working on the issue. I urge us to roll up our sleeves and get together to work out a piece of legislation that we can all work with.

Thank you.

[The prepared statement of Mr. Olson appears at the conclusion of the hearing.]

Mr. STENHOLM. Mr. Jay Feldman, executive director, National Coalition Against the Misuse of Pesticides.

Mr. Feldman.

STATEMENT OF JAY FELDMAN, EXECUTIVE DIRECTOR, NATIONAL COALITION AGAINST THE MISUSE OF PESTICIDES

Mr. FELDMAN. Good morning. Mr. Chairman, I would congratulate you again on your new position as chairman. Given your active participation as a member of this subcommittee over the years, I know that you enter this job knowing what you are getting yourself into. And we look forward to working with you to address the challenges that lie ahead and to address critical health, safety, and environmental protection needs.

As you know, probably better than most, we have experienced a logjam in the area of pesticide control and protections that have stalled health and safety reviews, we believe, and locked pest managers into pesticide-dependent systems.

The numbers of people in the pesticide community, farm and urban, will support an aggressive agenda, we believe, that moves this country away from pesticide-dependent pest management. We face some pressures now that may appear painful and overwhelming to the chemical intensive agricultural sector. The *Les v. Reilly* decision requires the enforcement of the Delaney clause and the minor-use pesticides. Both of these situations can and should be seen as opportunities for the transition away from chemicals which most people say they would rather not use or be exposed to.

There will be groups of vested interest that you will hear from today—I already see the boxes in front of us—who will staunchly defend current pesticide-dependent practices and resist the move away from pesticides. And they will paint a picture of full knowledge of pesticide toxicity and exposure, when this subcommittee has documented over the years the known risks and uncertainty that plague pesticide regulation, including the setting of acceptable risk and exposure levels. There are those who will argue that the uncertainty surrounding many pesticide risks is justification for continued pesticide use rather than reason to curtail use in deference to protecting people and the environment.

In this climate, we believe people will not accept a rollback in the protection of the current law, either through a delayed reregistration, reduced testing requirements under FIFRA, or reductions in requirements under the Food, Drug, and Cosmetic Act.

We are calling for the Congress and the Clinton administration to meet the statutory goals of these laws by assigning necessary resources and priorities.

Over its 12-year history, we have developed a broad, bipartisan constituency of those that experienced the problems of pesticide and the alternatives of practices that are not reliant on pesticides.

One that I believe you should consider is the fact that pesticide dependency in this country is increasing. While we have debated FIFRA over the years, pesticide use has gone up.

I direct your attention to a study by Public Voice for Food and Health Policy, "Agrichemicals in America: Farmers' Reliance on Pesticides and Fertilizers." The results are astounding.

"Different categories of agrichemicals have experienced different growth rates in the past decade: Fungicide use has doubled, herbicide and fertilizer use has grown slowly, and insecticide use has remained stable following a decline in the early 1980's due to the banning of toxaphene." If you take toxaphene out, insecticide use is stable.

More disturbing is the percentage of cropland treated with agrichemicals and the fact that is on the rise, according to the report. And our conclusion from this—and I think the subcommittee ought to seriously look at this—is as our Nation's agricultural dependence on pesticides increases on a treated acreage basis, we must ask if our national policy is moving agriculture in the right direction. Is this what we want to be doing?

FIFRA provides agriculture overall with the wrong orientation, promoting pesticides instead of pest management.

I, as you know, Mr. Chairman, have spent a lot of energy with growers in Florida who have experienced the downside of reregistration problems and had their crops wiped out as a result of the use of Benlate it is one of the hundreds of pesticides in the reregistration. It exemplifies the failure of this program.

Having said that and introduced into the record the facts behind that situation, I would like to point your attention to the issues that GAO has brought to our attention in their April 1993 report: "Lawn Care Pesticides: Reregistration Falls Behind and Exposure Effects Are Uncertain."

In there, there is a scathing indictment of what has been going on: One, EPA has failed to meet statutorily imposed deadlines that this subcommittee struggled with back in 1988; and two, we have seen—or GAO has documented a reduction in data requirements as part of an effort to speed up reregistration to meet those deadlines. And GAO says in its report that it cites EPA concurrence with the facts that they have presented.

To evaluate EPA's reregistration efforts, we must review EPA's efforts in three areas: toxicity, environmental fate, and exposure.

We have established that EPA is behind schedule. According to GAO. Since March of 1991, EPA's scheduled study completion dates for many of the 18 major lawn care pesticides have slipped significantly, some by as much as 4 years.

The same can be said for food use pesticides. You have GAO, in February of 1992; and they told you that EPA will not meet the 1997 reregistration timeframe established by FIFRA '88 for food use pesticides.

Now, as a result of this and the pressures that we are seeing, we believe there is a deficiency in the review process. EPA, according to GAO, has changed the basis of making reregistration decisions from fully—I underscore fully—complete to substantially complete data bases.

With Isofenphos, the registrant made up 24 months of slippage when EPA determined that it did not need spray drift studies due in 1995. EPA told GAO that it might make decisions without a groundwater study on Diazinon or a cancer study on Atrazine metabolite. This is astounding.

EPA doesn't have adequate exposure data to make decisions. Going back to the February testimony of GAO, the agency indicated that EPA did not have reliable data on the quantity of pesticides used on food crops.

"Our recent work on EPA's use of USDA's Nationwide Food Consumption Survey illustrates how inadequate knowledge may affect pesticide risk estimates. To establish safe levels of pesticide residues in or on food, EPA estimates dietary exposure to pesticide residues using data from USDA's survey, which is conducted every 10 years. However, we found that EPA's estimate of potential human exposure to pesticide residues in food is uncertain because these surveys of flawed."

So what is the value of the exposure data?

Similarly, with nondietary exposure, EPA has poor exposure data to use for purposes of reregistration because the Agency assumed that significant exposure was unlikely. Many in the Agency now have reversed that position.

A little diversion here, Congressman. I would like to say that farmworkers in this picture haven't been adequately protected even under the new work protection safeguards. We believe that farmworkers would be better trained if they were provided the same protection of other workers. Our country's "harvest of shame" must be addressed within the context of reregistration to ensure the well-being of those that harvest the Nation's food.

There, too, exposure data is not good. This subcommittee must address the integrity of test data. That is still an issue.

The inspector general brought this to you and the EPA's attention in 1991 with the inadequate auditing of test laboratories. The resources are necessary if we are going to meet the FIFRA '88 goals. EPA was in here at the end of 1991 saying that, "* * * we project a \$50 to \$55 million deficit for the reregistration program through 1997." We can't get the job done without the resources. That is not to say that EPA could not run this program with a firmer hand. EPA must be more aggressive in the enforcement of reregistration deadlines imposed on registrants, in addition to the funding issue.

I would like to move on to minor-use issues.

Mr. Chairman, minor use is a condition, I believe, that happens when you address reregistration in a vacuum without looking at alternatives and preparing for the transition to alternatives.

We are 5 years into the FIFRA '88 reregistration program, behind schedule, and deficient in our Nation's ability to protect against deadly pesticides. We should be facing up to the challenge of finding alternative methods of pest management.

As you know, minor use is not a minor exposure. Minor crops in California account for 89 percent of the total value of the top 15 crops. Nearly all crops grown in the Pacific Northwest are considered minor use. These are major exposure crops.

Our testimony addresses the fact that minor-use pesticides are not the way to deal with resistance management. Continued reliance on minor-use pesticides will undermine alternatives. We present to you an action plan for supporting a minor-use program that finds alternative approaches rather than one that simply postpones the inevitable cancellation, with no progress toward the development of alternative pest management options.

I would like to end that point and stress that we, Mr. Chairman and members of this subcommittee, believe that we have a tremendous opportunity to promote alternatives to pesticide reliance and significantly reduce pesticide dependency in this country through the reregistration prospects.

Thank you.

[The prepared statement of Mr. Feldman appears at the conclusion of the hearing.]

Mr. STENHOLM. Mr. Richard Wiles, director of agricultural pollution prevention project, Center for Resource Economics, accompanied by Ken Cook.

STATEMENT OF RICHARD WILES, DIRECTOR, AGRICULTURAL POLLUTION PREVENTION PROJECT, CENTER FOR RESOURCE ECONOMICS, ACCOMPANIED BY KENNETH A. COOK, VICE PRESIDENT, POLICY, AND ON BEHALF OF CHRISTOPHER CAMPBELL, RESEARCH ASSISTANT

Mr. WILES. Thank you for the opportunity to testify today. I am presenting testimony on behalf of my colleagues Ken Cook and Chris Campbell. We look forward to working with you on the issues in the coming months.

We look forward to working with you, Mr. Chairman, and with other members of this subcommittee in the months ahead on the full range of FIFRA reauthorization issues.

Recent research at the center has focused on several topics that relate directly to the subjects to today's hearing. Of particular relevance is a report that we are now finalizing on pesticide residue levels detected in fruits and vegetables that are consumed in large quantities by infants and by children under 5 years of age.

Our report, to be released later this month, will analyze patterns of infant and child exposure to a variety of pesticides in the food and water. We will also present estimates of the cancer risk to young children that is associated with those patterns of dietary exposure.

Our testimony today focuses on two interrelated observations that arise from our research. We offer them as a point of departure for the subcommittee as it takes up FIFRA reform.

First, our research indicates that the U.S. population, and young children in particular, are being exposed to low levels of scores of different pesticides in the food supply with far greater frequency than was previously recognized.

Second, if the weight of the evidence does suggest that children exhibit special sensitivity to pesticides and other toxins, even at the low doses typically encountered in food, then the exposure patterns that we have found will raise important public health questions for pesticide policy, including registration and reregistration.

We would like to emphasize, however, that these observations do not justify abrupt or immediate changes in personal eating habits. We do believe, however, that they justify major and fundamental reforms of pesticide policy in order to reduce, systemically, the real, albeit chronic, risks posed to children by low levels of pesticides in the food they eat.

Dietary exposure to pesticides is a central issue in pesticide registration and reregistration. The setting of tolerances that protected the public health, after all, is one of the primary goals of the entire reregistration process. Determinations of dietary exposure is especially important for minor-use crops—a distinctly misleading term we might note. Crops that are minor use in terms of acreage treated with pesticide are often major league in other respects, notably in the volume of pesticides applied, the magnitude of infant and child consumption; the extent of worker exposure and the extent to which farmers now rely on high toxicity pesticides for pest control.

Our analysis of test data from commercial and private sector labs indicates that pesticides occur in many fresh fruits and vegetables with greater frequency than the FDA has reported in the past.

It is our understanding that the Department of Agriculture is soon to release its 1992 report for the pesticide data program and that the report will reinforce our analysis of pesticide residue data from commercial laboratories.

As you develop amendments to FIFRA, we urge that the committee review recommendations from our study regarding the occurrence of pesticides in the food supply. This information should be reviewed against the backdrop of the National Academy's report on methodologies for assessing risks to children from pesticides.

It is our view that a new framework for evaluating pesticides will result as a deeper understanding of the risks of pesticides. That framework is built on emerging information about the prevalence of low levels of pesticide residues in the food supply; a clearer understanding of food consumption patterns, especially among infants and young children; and emerging scientific understanding about the risks that pesticides and other toxins pose to young children and other sensitive subgroups of the population.

Among the implications of this framework are the following:

Pesticide tolerances will likely have to be lowered significantly for many compounds.

A number of pesticides likely will have to be phased out, as the risk they present in the food supply or in drinking water is too great to perpetuate their use.

In responding to this policy framework, however, EPA will have an opportunity to increase program efficiency and provide greater benefits to farmers and the public health by focusing limited reregistration resources on crops most dependent on high risk pesticides.

Thank you.

[The prepared statement of Mr. Wiles appears at the conclusion of the hearing.]

Mr. STENHOLM. Thank you.

Mr. Smith.

Mr. SMITH. Thank you, Mr. Chairman.

Ms. Hinkle, do you believe that Delaney ought to be rewritten or revised?

Ms. HINKLE. I think the language itself is good. I think how it has been implemented since 1958 is a disaster. And that was pointed out by the National Academy of Sciences in its study of the "Delaney Paradox" that we have an inconsistent standard between raw and processed food since Delaney only applies to processed foods and there are many foods that are indistinguishable as to when pesticides are applied and when they are consumed.

So the thrust of the Delaney study at the academy, which Richard Wiles worked on, is that, by establishing a clear, consistent, and firm standard, we could effect greater protection of humans from carcinogenic pesticides.

Mr. SMITH. I am not sure you answered my question.

Ms. HINKLE. Well, the answer is—

Mr. SMITH. Should the tolerances in Delaney be changed? And if so, which direction, I might add?

Ms. HINKLE. Delaney states that the standard for carcinogenic substances added to food should be zero.

Mr. SMITH. I understand that.

All right. Anybody else want to—

Mr. OLSON. I would be happy to take that question. It is our view that the Delaney clause, as it is written, is not a bad thing; but it embodies a policy that we should not be purposefully adding carcinogens to our food supply.

What we have said repeatedly before this subcommittee and other subcommittees is that, as part of an overall package that adopts broad protection for the public's food supply, we are willing to live with an amendment of Delaney that would embody something in the likeness of the Kennedy-Waxman legislation; although we would like the Kennedy-Waxman legislation to be enhanced with an ultimate phase out of carcinogens over some reasonable period of time that allows for the rise and development of alternatives to those chemicals so that farmers have the alternative to shift to alternatives in a reasonable period of time.

Mr. SMITH. Are there any good pesticides?

Mr. OLSON. Yes. We are not taking the position that all pesticides should be banned. We are saying that the Agency needs to look at pesticides that do pose risks with farmworkers with dietary risks and other points.

Mr. SMITH. I think we all agree to that.

I guess the question is, who measures the risk; and who do you believe in this process?

If I were you folks, I wouldn't want to change FIFRA at all; it looks like you are winning. You can't hardly reregister a chemical anymore. And if you do, it costs too much, and you wait too long.

Would you favor helping to reduce the time that the pesticide may be reregistered as well as reducing the time of enforcement?

Mr. OLSON. I am not sure I understand.

Mr. SMITH. Somebody complained that enforcement took 4 to 8 years, and that is too long. Registration may never happen, and that is too long.

Mr. OLSON. We agree that the reregistration process is taking too long, and we are concerned about that.

We are also concerned—the statement that I read from former Administrator Reilly, that once EPA determined that the chemical poses a problem, his complaint was that it takes 4 to 8 years for action on that.

We don't believe that we are winning under FIFRA. We believe that the process created undue delays. And once the Agency makes a determination, yes, there needs to be procedural due process under the constitution. But we believe that 4 to 8 years plus—that is an estimate in some cases—is really too long.

Mr. SMITH. Mr. Feldman, you cited an ongoing 20-year study.

In the last 2 or 3 years, has the use of pesticides increased, or is it topping and going down?

Mr. FELDMAN. The use of pesticides over the last decade has increased. There are fluctuations.

Mr. SMITH. In the past 2 or 3 years?

Mr. FELDMAN. I believe there has been a stabilization. And we believe that is due to the switching to low-volume pesticides such as sulfonated urea pesticides. And in many cases we might be comparing apples and oranges.

Mr. SMITH. I don't think it makes a lot of difference. I mean, if they are dangerous, they are dangerous whether going up or down.

Mr. FELDMAN. The point is, we started this hearing with a rather good statement from the chairman that indicated——

Mr. SMITH. And my statement, as well.

Mr. FELDMAN. And your statement as well—that nobody wants to use pesticides. Yours is in the record. I assume it says the same thing.

But the point is that we are not, in our organization, taking the position that farmers should not have the access to the tools that they need to meet their pest control goals.

We don't believe that the rule is aiding farmers in introducing into the market chemicals that may cause cancer, which, in fact, we haven't even evaluated the need for those chemicals in light of the range of alternatives that are there.

So the point of the study, in the last 3 years, is that there is an increasing dependency on a per-acreage basis on pesticides.

We are not moving away from the reliance that every grower would like to do. And the law, in many ways, is preventing that from happening.

Mr. STENHOLM. Mr. Dooley.

Mr. DOOLEY. Yes.

Ms. Hinkle, I was interested in some of the reporting reforms that you were advocating. And being from the State of California, we have in place what I think are probably, throughout the Nation, the most stringent reporting inventory monitoring standards.

Are those, in your opinion, adequate? And if not, what would need to be changed in those?

Ms. HINKLE. I think so.

I like to buy produce from California because of your reporting system. So whenever I see a California brand A, as opposed to a brand from another State—if they say asparagus from California, then I tend to trust it more, even though I don't know what is on it. I know that whoever grew it was required to report whatever he used on that crop.

It is an elaborate system which rests on an infrastructure that preexisted the establishment of the recordkeeping requirements. I am not sure that the same system could be done nationally. But what I am asking for is that general use, as well as restricted use pesticides, be required to be reported because restricted use pesticides only constitute 10 percent of all use.

So in order to get a real picture that will help the regulators and help agencies and the public at large, we really need to know where 100 percent of the pesticides are applied.

Also, we need more information than is now required in the law. The USDA officials who were trying to implement the record-keeping law said it is useless; it isn't going to give us useful information at all. So I discussed with them what kinds of information would be useful. I think that California requires much more, and I know that the State of Washington does. But what we want is the bare minimum.

And any State that wants to have more information, of course, can and should.

Mr. DOOLEY. So, by and large, you would be supportive of overlaying the inventory and reporting requirements already in place in California with national standards that will be acceptable and meet your organization's concerns?

Ms. HINKLE. Yes.

Mr. DOOLEY. Mr. Olson, on some of your comments relating to the adequacy of Delaney, I guess it comes back to the central point that it is really the dose that constitutes the toxin, oftentimes or whether or not a substance is poisonous; would you agree with that basic assumption?

Mr. OLSON. Our concern is twofold; that is, currently we don't know what the dose is. We don't know at what level people are being exposed. We are guessing, based on some data, that, as Richard suggested in his statement, it is considered to be inadequate. We are concerned that, in most cases, people are not being exposed with single chemicals or single residues; but if you pick up an apple or sit down and eat a meal, the foods that are eaten probably do have multiple residues on them. And it is difficult to pinpoint precisely what the risk is from being exposed to three, five, or seven different pesticides in one meal.

So our concern is that we would like to see something along the lines of Kennedy-Waxman as a step in the right direction that would establish, at least up front, a maximum allowable residue level for that particular pesticide.

Mr. DOOLEY. I guess my concern is that the present requirements for the registration of a chemical or pesticide, whatever it may be, are that they are required, the manufacturer, the registrant, is required to go through the studies using the maximum tolerated dose, which is basically whatever you can give a rat before it dies and still stays alive, which then creates a situation where it looks to me that you get an obligation of what would be normal data.

I have some questions and concerns about the validity of that. Especially if they are running two other test cases which would be expected maximum dose and there is no incidences of cancer and, at lower exposure, there is no incidences of tumors that are cre-

ated. Do we, in fact, have a system now that is, perhaps, I think, grossly overstating the incidences of cancer and tumors that are created by a lot of these products that are going through registration?

Mr. OLSON. I would urge to you to take a look at the National Cancer Society's report on the maximum tolerated dose.

I am not an expert in this area, but if you read that report, what it said was that although MTD testing is not perfect, it is not ideal. It is basically what we have. And it is something that the academy recommended that we continue to use.

There was some dissent from some of the industry representatives.

Mr. DOOLEY. There was also a statement made by, I guess it was the board of the National Toxic—it was part of the EPA—I guess they have an advisory board that stated that two-thirds of the chemicals that were acknowledged as being carcinogenic in this testing process, that under normal testing processes—or ones that didn't include this maximum tolerated dose would never have been classified that.

From what I understand, the MTD is not internationally accepted protocol because a lot of countries have come to the same conclusion: If you fed a rat massive doses of salt that allowed them to live but made them very sick, they are going to come down with a lot of other things.

It distorts the validity of that determination.

Mr. OLSON. I would ask Richard to respond, but let me make two points.

One is that the National Academy of Sciences' report looked at that very issue and determined that we are stuck with it. It is the best thing we have. And the reason for that is, unless you have mega mouse studies where you dose thousands or hundreds of thousands of animals, you are stuck with using high levels, high doses; otherwise you will never find a 1 in 10,000 risk or 2 in 1 million risk unless you test millions of animals. That is why they have to apply the high doses. Otherwise, they would have to spend hundreds of millions of dollars for each chemical. That is the reason they apply the high doses, to come up with the curves. And that is discussed in the academy report.

The other point is that, internationally, judges, a lot of other countries do rely on OTD and do rely on animal testing. Unless you wait until you have human evidence, epidemiological studies showing cancer—which in our view is too late—you have to rely on animal testing.

Mr. WILES. Congressman, I would like to make a point: I think you have here a classic example of what we want to move away from. The Agency and the current system focuses far too much attention and resources on determining the significance of high dose cancer studies. What we need to do is implement a policy that is preventative in nature and uses these studies appropriately.

I think we would all agree that these studies, in spite of all their shortcomings, help us establish priorities in terms of which chemicals are the most toxic. And from that point, we would argue that the most toxic compounds should be reduced and phased out over a determined period of time rather than arguing about the signifi-

cance of exposures in animal studies at doses that we all agree are very high and not particularly relevant to human situations.

Mr. STENHOLM. Mr. Canady.

Mr. CANADY. Thank you, Mr. Chairman.

Ms. Hinkle, I have a question for you about a concept that is addressed in your testimony. That is the concept of realistic yield goals. I am not sure I understand that concept.

And exactly what standards would be used in determining realistic yield goals? And what type of data would we need to empirically establish realistic yield goals?

I would appreciate it if you could address that.

Ms. HINKLE. Currently, in several parts of the country, there are studies underway showing that there is a limit beyond which, if you apply additional nitrogen and agricultural chemicals, you have to apply so much more of the chemical in order to get a yield response, that that maximum efficiency has been reached.

In other words you are wasting more—

Mr. CANADY. Sort of the diminishing return concept?

Ms. HINKLE. Yes. The studies I have read are very persuasive. But EPA has interpreted benefits as increased yields per acre, per year. Even though yields were frozen at 1986, nevertheless, what they were using in 1986 may not be the limit beyond which they don't need to apply additional chemicals.

Mr. CANADY. When you address this concept, you link it to a replacement for annual set asides as a production control device.

Would you say that this concept would not be applicable where set asides are not already in place?

Ms. HINKLE. These maximum yield benefits are already being pursued in some areas of the country.

Mr. CANADY. Who is pursuing that?

Ms. HINKLE. Nebraska. Iowa. I will be glad to look them up for you.

Mr. CANADY. Is it a voluntary manner, as an economic matter?

Ms. HINKLE. An economic matter, economic efficiency. They are not tied to set asides. I simply threw that out so that realistic yield goals could be viewed as an alternative to set-aside programs, because the set-aside programs have tended to increase the intensity of cropping on the crop land that is in production.

Mr. CANADY. Thank you.

Mr. STENHOLM. Mr. English.

Mr. ENGLISH. Thank you, Mr. Chairman. One of the problems that we have is striking a balance between any potential problems that we might have from an environmental or health standpoint and with, of course, income to farmers. That is a very delicate balance to strike.

As we move along, it appears that we are finding ourselves more and more often in areas where there seems to be disagreement among experts. Or if there are projections that there may be a problem, there is no certainty of the problem, or there is a question with regard to levels. The farmers may use a particular pesticide; it may cause a problem.

It appears that our Government is more and more often erring on the side of caution, which may be the proper position from the standpoint of the Nation; but it does present a real problem as far

as farmers are concerned. You can imagine the frustration that a farmer may have if he has a serious problem. He knows what the remedy for that problem is, and he knows how to save his crop; but because there is a fear that a substance that he has used in the past may be a problem or a particular dosage may be a problem, he is prohibited from using that substance. And, of course, he must bear the economic loss. And that is where I see the dilemma that we are facing.

I wanted to ask each of you how you would feel about—should our Government—in these very gray, questionable areas, should our Government then compensate farmers in those cases in which they are prohibited from using substances in which there is no proof of difficulty, substances where we have prohibited the use because there may be a problem?

Ms. HINKLE. I don't know of an instance where use has been prohibited because of a possible problem. I think that where substances have been banned—in the case of DDT, even then, when there wasn't an alternative for onions in the Pacific Northwest, sweet peppers in the Delmarva Peninsula, then DDT was allowed to be used. There are other cases of heptachlor/chlordane. And each time that the issue was before the courts, the corn growers said that they would not be able to grow corn, that corn would absolutely not be able to be produced without the use of the chemicals being contested. And then they had bumper crops. This was in the mid-1970's.

So it is amazing what can be done, even when you have a banned substance. In the case of the onions, sweet potatoes, and green peppers, they did get an alternative within a year of the 1972 ban, and that was because companies knew there would be a market.

I think there can be a lot of technology forcing when farmers and companies know that there is going to be a substance no longer in use. But I also know of instances where EPA said that they might take action, which is similar to your scenario. Then companies and USDA went to work in a high gear mode to find alternatives. But then the rug was pulled out from under them, and the compound was reinstated.

And normally the product that is reinstated is very broad spectrum. Whereas the companies and USDA were working on specific and selective alternatives so their market was very small. And in the end, they didn't have the market.

Mr. ENGLISH. Let me give you an example of what I am talking about. In my district we, from time to time, have a very serious problem of blight in peanuts called sclerotium that occurs as a result of weather conditions. I believe they have this in Texas as well. What has been used for years is a substance known as Botran, which is very effective in dealing with sclerotium. The difficulty was that the company that produced Botran did not find it economically feasible with regard to peanuts. The outer shell—not the peanut inside—but in case the shell might be used as cattle feed down the road there might be a problem with it, we don't know.

Well, from an economic standpoint, it didn't make sense for this company to go through the tests that are required. EPA then, because of their rules and regulations, for several years had declared

this as an emergency to try to give assistance. They didn't feel there was going to be a problem with this. But the problem came back to the law, and the law said you have to go through all of this testing.

So here is the poor farmer caught in between. On the one hand we have a law that says you have to do the testing; and on the other hand, you have a company that says, this substance, we will quit using it, we won't sell it. We finally came down to what I think must have been a decade or better in which we have gone through this exercise with EPA leaning over backward to try to come up with some kind of declaration that allowed what they considered to be a substance that was not a problem in being applied to peanuts. They finally had to draw a line because we had a GAO report that pointed out that this was being done. And somebody here in Congress held it up—in another committee by the way—and said, hey, how come you are doing this? They beat the EPA over the head with it.

The difficulty comes down, that the company is not hurt because they didn't sell that much of it for this purpose anyway, and certainly the Government is not hurt, but that farmer sure is hurting.

Ms. HINKLE. The growers have been thrown overboard.

Mr. ENGLISH. There is nothing for them to use that we have found as of yet. There supposedly is a substance, if we can get that company to go out and do the testing on it.

The question that I have in my mind is when we find ourselves in these kinds of circumstances, particularly where there is no proof of it being a problem, if we are going to err on the side of caution, doesn't the farmer deserve some consideration? Doesn't he deserve compensation because of an act that we think possibly there is some kind of harm some place, some time?

Ms. HINKLE. The problem, Mr. English, is that the whole thrust of the 1972 amendments was to require testing of these products before they are marketed. Since most of the products that we are now talking about were registered previously, they have only to meet reregistration requirements. But they, nevertheless, have to meet the requirements of safety before they can be marketed.

The chemical companies only see an economic return in the major uses. Peanuts happens to be a minor use for them. Our problem is that they need to be tested just as much as the major uses. And that we are willing to give some relief to these growers, because that is where the relief is needed. The chemical companies are happily testing their major uses.

I think that IR-4 could do some of the testing. They could even assume registration as a registrant on behalf of the growers. I think we could work out some arrangement so that the testing is actually done and the value of the product can be pursued, and registration doesn't have to be sacrificed.

I would hope that any such minor uses could be put into an IPM program to reduce the use of the chemical to only when it is needed and that there be very accurate reporting requirements on such a use so that we have some kind of control over the situation.

Mr. ENGLISH. Thank you, Mr. Chairman. I appreciate it.

I appreciate your response, Ms. Hinkle. I think that is along the lines—we have to do something to address those kinds of situa-

tions. The farmer is not the one who should have to bear the burden.

Ms. HINKLE. You missed my testimony. But I think the minor-use growers and the minor-use registrants, have a lot in common with the biocontrol registrants. The target niche is very small; the market niche is small. The products tend to be very selective, and there is little or no commercial advantage. We have to provide incentives for these groups.

Mr. STENHOLM. Mr. Gunderson.

Mr. GUNDERSON. Thank you, Mr. Chairman.

I leaned over to Mr. Smith—listening to most of your testimony, and reading those of you who spoke before I came in—and I said, what makes this different than the other seven sessions in Congress I have sat through on FIFRA? And he said, nothing.

I think we have congressional gridlock on environmental policy, and FIFRA is the classic example.

My question to each of you is, frankly, why should we have hope that this year we can bring about some kind of political consensus on a FIFRA rewrite?

Ms. HINKLE. Because minor-use growers need relief. The Delaney fix needs to be attended to. EPA is notoriously inefficient. And as it assumes Cabinet status, it should look to trying to obtain greater efficiency than has been possible before. And that can only be done by accelerating the cancellation and registration procedures, increasing penalties and enforcement, and increasing fees so that they would have the resources to administer appropriately. And the companies are suffering from this paralysis equally.

Mr. GUNDERSON. So you are willing to support increasing both the registration and the cancellation process?

Ms. HINKLE. Well, the registration and reregistration were accelerated in 1988. That was the FIFRA lite.

Mr. GUNDERSON. So, in your opinion, that is already done. Now we will accelerate the cancellation?

Ms. HINKLE. Right.

Mr. GUNDERSON. How do I get a political compromise from both sides on that issue? You are saying to the industry, you have already gotten the acceleration of the registration and reregistration process; we are going to accelerate the cancellation process. What a deal.

Ms. HINKLE. They don't need the relief. But the minor users do.

Mr. GUNDERSON. Why would, then, industry buy that deal on behalf of the minor users?

Ms. HINKLE. They can continue to be resistant and not very tolerant of the minor uses. But I think that they should be more open-minded about that.

Mr. WILES. We think that perhaps the interests of the minor users and the interests of the public coincide here and that the chemical companies may not have an interest in addressing the legitimate needs of minor use growers. But we feel it is a very serious problem, and that the National Academy of Sciences' report, that will undoubtedly address the issue of children, may provide an opportunity to resolve both the minor use issue as well as the pressing public health issues.

Mr. GUNDERSON. I am delighted to hear from any of you. Otherwise I am going to continue to express my frustration with this process. I am willing to put as much time into this as anyone if I see any good faith effort by anyone on either side to reach consensus. I have not seen that in the—now the seventh term I have sat on this committee and this subcommittee. I am trying to find out from somebody, give me some reasons that we are nearer this time; otherwise I am going to go do something else.

Mr. FELDMAN. You have been involved in this debate, and you were active in the FIFRA '88 discussion. And in the context of what we all felt was necessary to make safety determinations and do it in a manner that was responsive to grower needs and pest manager needs, FIFRA '88 was adopted as a compromise. It was FIFRA lite, streamlined to zero in on those issues that we could all agree on.

What is frustrating to me in that process is now, as we have moved along and the requirements are being imposed or we are trying to get them enforced, we are seeing that those that were party to that discussion feel that it is not workable, that it can't really serve the interests of growers. That is frustrating.

I think my frustration and the frustration in these discussions on reregistration is that it is not linked to the assistance that growers need should those pesticides fall off the list. The commonality that all the folks in this room have, at least the growers and the environmentalists, is finding the solutions to those pesticides that don't meet the concerns that you addressed and I addressed and others addressed in 1988 when we brought into the concept of meeting basic health and safety standards.

The difference now is that there is a lot of pressure on the grower community, through no fault of their own. I think there is a bigger split between the growers and the chemical companies. I think that their interests are not always in common, which this committee has not always recognized and which we may have to recognize now, quite frankly and that once you separate it all out, you will find that the growers seeking to get off the pesticide treadmill; and the environmentalists seeking to improve public health and environmental protection, will join together to form compromises to ensure that the tools are available to meet pest management problems.

Now what that does for the agrichemical industry and product sales may not always be a pretty picture. And that is where the difficulty comes that companies that have relied on pesticide sales may find that the market isn't there long term. And I think many of them have already shifted out to other sorts of products and have diversified because of that.

So it depends who you define as a constituency. If you define it as growers, farmers, pest managers, the potential there is stronger than it ever has been. The potentials that Richard mentioned are going to facilitate the coalition coming together.

Mr. GUNDERSON. I am out of time, but I am wondering if you would consider submitting a letter or memo to this subcommittee on what you believe are the issues that could be a part of a compromise in this session of Congress. If we understood exactly where

people felt there was room to talk, then we could make some progress. Is that an acceptable question?

I understand that everybody gets up and gives their wish list of advocacy positions. That is fine. That is part of the process. Now that we are done with that, you talked funding, you talked accelerating the process, things like that. Are there areas where we might find some kind of middle ground this session so that we can really do something?

Thank you, Mr. Chairman.

Mr. STENHOLM. Mr. Allard.

Mr. ALLARD. Thank you, Mr. Chairman.

I would like to address my first question to Mr. Olson. And this question was brought up on your discussion of the Delaney clause and some of the things where we talked about toxic levels.

But do you believe that a substance at higher levels that may be carcinogenic at a lower level, may pose a negligible risk or may lose its ability to cause cancer?

Would you agree with that?

Mr. OLSON. Well, what I would go back to is the National Academy of Sciences report said—that came out earlier this year—which was that because of the vagaries of animal testing, we are forced, unless we want to test hundreds and hundreds of animals, to test at relatively high levels to find these risks.

Mr. ALLARD. But that wasn't my question.

Mr. OLSON. Let me continue. At lower levels of exposure, one would extrapolate from the high levels of exposure backwards. And that is traditionally how public health officials have done this kind of analysis, is by saying, well, we have models that suggest that a single hit of a carcinogen on the DNA is enough to cause a tumor; and, therefore, we will assume as a matter of public safety, that that model works. And then they try to fit the curve of the various exposure levels to that.

In direct answer to your question, there is a lot of research going on right now as to whether there are thresholds for some carcinogens. It may end up being proven that there are some carcinogens that do not, acting alone, serve as a carcinogen at extremely low levels. But I don't think the data is in on that. The best minds in the country and the world are working on that issue, and I am not one of the best minds in the country on that issue. So I would have to say that the evidence is not in on that yet.

And in the meantime, we ought to be taking the prudent approach, which is protection until it is proven that the opposite is the case. We shouldn't just assume that these are not carcinogens, contrary to over 30 years of public policy, until it is proven that they are not.

Mr. ALLARD. So Congressman Gunderson was talking about areas that could be discussed and where issues could be resolved. And I see the big one is the Delaney clause. And you are not willing—or anybody at that table—willing to make the assumption that there is a reduction in risk with reduction in dosage?

Mr. OLSON. No, I think you are misunderstanding me. Of course there is a reduction of risk in reduction of exposure. We believe in a dose response curve which suggests that the more concentration, the higher the risk; the lower the concentration, the lower the risk.

Mr. ALLARD. And you do reach a point where risk becomes negligible?

Mr. OLSON. The question is: At what point can you say that the risk is negligible.

In answering previous questions of Mr. Dooley, what I said was that the complicating factor here is that people are not exposed to a single carcinogen at once. They are exposed to dozens, in some cases, in a single meal.

Mr. ALLARD. How can you make your scientific data reflect that multiple exposure?

Mr. OLSON. That is why, as an interim measure, you try to get the risks down. But over the long run, we ought to be shifting to alternatives so that we don't argue on how many angels are dancing on the head of a pin.

Mr. ALLARD. What alternatives would you suggest?

Mr. OLSON. I think there are a lot of alternatives, and that is one of our frustrations with FIFRA.

Mr. ALLARD. I think that part of the problem with registration process is that manufacturers are telling me that we do have some alternatives, but the registration process is so complicated that we can't get these where we can get them marketed because of the extensive testing that has to go on.

And it seems that we have worked ourselves into a corner, and it is very difficult to come out with any kind of common sense solution.

And I am looking for members at that table to suggest how we can come up with a common sense solution.

Mr. OLSON. We certainly support trying to expedite the process of registering new niche pesticides that are safer than the ones on the market now. We believe that there is a need to shift EPA resources into developing nonchemical and chemical alternatives to the problems of pesticides. The problem has been that the users of pesticides are left in a lurch in many cases whether EPA giving them a heads-up saying that in several years from now chemical *x* is going to be yanked from the market. But the resources aren't expended on developing those alternatives and then there is a crisis at the end of pipeline.

We think there is both a need to expedite the registration of the safer alternatives and the need to expedite the exploration of nonchemical alternatives through USDA and EPA.

Mr. WILES. Congressman, let me suggest that the best way to create a market for a new, safer compound is to remove an older, high-risk compound from that market niche. If you want to see product development and product innovation in herbicides, which is a multimillion-dollar market, you have to create an opening. And the way to do that is to begin to address the high risks posed by the currently used chemicals compared to the chemicals that are waiting to break into that market niche.

You will never see those new chemicals break into that market share until that kind of action is taken.

Mr. ALLARD. My time is up, but I would just like to make a statement for the record.

I think it was you, Mr. Wiles, who made the statement that agriculture's dependency is pesticides. I think it is more of a depend-

ency of the American public wanting to depend on a large variety of good-tasting foods that look good and are nutritious and in abundant supply. I think the agricultural community is just trying to meet that demand.

So I would hope that we recognize that the agricultural community wants a safe food supply, but I think what they are calling for is a common sense solution. When we get into things like the Delaney clause or things like the statement that I heard here—absolutely no chemicals in the food—food is made up of chemicals, water, and carbon compounds. Technically they are all chemicals. But I think there needs to be some moderation in the rhetoric that is going to indicate some willingness to come to a compromise before we are going to come up with something that will eliminate the deadlock that Congressman Gunderson was referring to.

Thank you very much, Mr. Chairman.

Mr. STENHOLM. Is it really possible for this committee of this Congress or this administration to create a zero tolerance for carcinogens in our food supply and have it stick?

Mr. WILES. I would say that, over the long term, yes, it is possible to do that.

Mr. STENHOLM. How can we do that when carcinogens occur naturally in the environment and with modern technology we are capable of measuring parts that are so small that I can't pronounce the number? How can you say it is possible to have zero tolerance?

Do all the rest of you agree with that statement that it is possible to have zero tolerance established and administered?

Mr. OLSON. When you speak of a tolerance, you are talking of something that is purposefully added to the food. And, yes, it is possible to establish a tolerance of zero.

But rather than thinking of it in terms of establishing zero tolerances, we are urging that we identify the risky compounds and move toward alternatives of those compounds in a reasonable period of time.

Mr. STENHOLM. I understand that, and you have answered the question.

Mr. Feldman, you answered the question. You are saying that it is possible to assure the American public that there is zero carcinogen in their food supply?

Mr. FELDMAN. It is possible to take a position from this point forward we will not intentionally add additional risk. It is not possible to assure the public that there is zero carcinogen in their food. DDT is the second most commonly found pesticide after malathion. DDT is a carcinogen according to EPA. So it is not possible—

Mr. STENHOLM. Is there any scientific evidence as yet to show that the human body reacts to natural carcinogens differently than man-made carcinogens?

Do any of you know that?

Ms. HINKLE. No. The etiology of cancer is very complex and mysterious and remains mystifying.

Mr. Chairman, the way I look at this is that cancer claims 1,000 lives a day. It is a very serious disease that we really don't want to have. To the degree that we can meaningfully remove these substances that are deliberately added and to which people are unwittingly exposed, it is only prudent policy to do so.

Mr. STENHOLM. I certainly do not disagree with that statement.

I want to follow up with each of you, getting at Mr. Gunderson's frustration over the last several years. And it is also a frustration I think we are all going to have to address; this panel, the next panel, and the panel after that and this subcommittee. When we start talking about alternative pest control agents, lower risk pesticides, safer pesticides, new generation pesticides, biological control: Each of these will possess an unknown, perhaps dangerous side effect, and will also be attacked by many as being less than desirable for human consumption and must be tested.

Agree?

Ms. HINKLE. There is an existing knowledge base for chemicals. We have a 50-year investment by the Government and by the companies in chemicals. There is an enormous knowledge base that generates and promotes chemicals. There isn't the knowledge base for biologically based substances. It is very sparse. We do have some of it in regard to breeding. And we are getting some in plant genomapping.

But the counterpart for biologically based pesticides simply doesn't exist. Yes, we have had biological controls for 100 years. But 50 years ago, the research and development of some of those just wasn't done. Only when we have an emergency like the Russian wheat aphid or the sweetpotato whitefly do we launch an all out effort to try to find biological controls and to breed resistance into the plants.

And in any case, we need to do this predictably ahead of time. We can't wait until a pest becomes an emergency and then launch an all out, very expensive program. We need to develop this biology knowledge base now. And we can and we are doing it a little bit. It is just that it is so little. And it is not enough to take care of the problems that we have with resistance and with alien pests which truly are invading our country. And they come here without their natural enemies, so their population growth is uncurbed, unrestrained. And they become very notorious pests.

Mr. STENHOLM. I thank you all for your testimony this morning. You know, the basic—I don't like to use the word problem—opportunity that we have as we begin this session in attempting to address these questions is finding not a middle ground but a common sense foundation to build from that we can agree to.

That is why I asked the question about zero tolerance. To me, when anyone suggests that we can have zero tolerance for carcinogens, that defies all knowledge that I have. It is impossible to do that.

Mr. Wiles, you wanted to say something?

Mr. WILES. I wanted to clarify that. I dug myself a fairly deep trench, and I would like a chance to climb out. What I meant was that we could put in place policies that move us away and ultimately stop the adding of carcinogenic pesticides to the food supply.

Mr. STENHOLM. And that is a good way to dig yourself out. We want to start out on level ground.

Mr. WILES. Absolutely.

Mr. STENHOLM. Mr. Smith, one final question?

Mr. SMITH. Thank you, Mr. Chairman.

Mr. Olson, do you think we should continue using MTD, or maximum tolerated dose, as the gauge level for animal carcinogens?

Mr. OLSON. All I can say is that the most esteemed group of people that I am aware of who looked at that from the National Academy of Sciences said that, yes, although it is not perfect, it is what we have and that we ought to continue using it until we have something better.

Mr. SMITH. I want to read to you from the National Academy of Sciences, which you have been quoting all day, risk assessment, the first paragraph in their conclusions: "Several decades ago there was no standard for biotesting chemical carcinogens. The current MTD bioassay in rodents closed that gap and became a standard in the United States. It is neither perfect nor unalterable and, by itself, is insufficient to produce data from which accurate human health risk assessments can be made."

Now, if this is the source that we have to depend on—and it is insufficient—how in the world are we going to make decisions on these very difficult programs when the source that you have identified says it is insufficient?

Mr. OLSON. It is insufficient. And that is the whole point.

Mr. SMITH. And you agree with that?

Mr. OLSON. Yes, we agree that it is not sufficient in and of itself. We ought to be moving toward better data collection.

Mr. SMITH. We are a rather bright panel, with one exception, the one speaking. But if you rely on this kind of source to make a decision, you are relying on insufficient data.

How in the world are we going to get to a point where we make an informed decision?

Mr. COOK. If what you are suggesting is that we not use that standard, one of the affects of that, if we have nothing else in its place, would be to immediately remove dozens and dozens of pesticides from commerce. I don't know about the ones that are stacked up—the registrations that are stacked up in this box here. I am sure they are very costly to acquire.

But what the public has decided in setting the Delaney policy long ago—and what we are grappling with now—suggests that we have been cautious in the past, but in many cases we have not been cautious enough. Perhaps in some cases we have been too cautious; but if we start throwing out the protocols on which all of these compounds are based and we are going to go to the public and say—

Mr. SMITH. Let me read you another sentence of this magic study that everybody is supposed to follow. "The use of MTD itself will not predict whether the material will elicit a carcinogen response in a standard animal bioassay."

So, you can't depend on it. It doesn't elicit a response. You can't predict. You can't predict the response it will elicit. Therefore, it is unpredictable. Therefore, the standard we use is unreliable, insufficient, and unpredictable.

Mr. COOK. So what would you have us do in face of that? It may be the Delaney clause.

Mr. SMITH. But don't continue to use this as a source and the only source. You have to be careful about using responses from reports because people read them.

Mr. OLSON. I would like to respond to that. I think what that report said, as I repeatedly said, was that it was not perfect, but it is what we have. It is the only thing we have, unless we end up relying on something else. And the something else would either be human epidemiological evidence where you wait until people are exposed, you wait until they get cancer, and then you count up the cancers, which in our view is not a prudent policy. Or you come up with some other paradigm for testing. It could be human being tissue testing; it could be any other number of items. But there are problems with everything.

I have read the report, and it points out all sorts of problems with MTD and other approaches to animal testing. Unfortunately it is all that we have right now. And there was a split in the academy panel. And the ultimate major opinion was that that is what we were stuck with.

Mr. SMITH. It was 11 to 6. That was the split.

Mr. STENHOLM. Mr. Dooley.

Mr. DOOLEY. Just quickly to follow up on Mr. Gunderson and Mr. Stenholm trying to find agreement, I have heard of moving to safer alternatives. I am interested in those, and I am intrigued by some of the advances in biotechnology that are creating crops that have more tolerance to some of the pests that are causing the problems.

Is this an area where potentially we could find a way to expedite the registration of some of these genetic advances that we are seeing in the biotech field that could be a safer alternative?

Would this be an area which you folks would be interested in supporting?

Ms. HINKLE. Yes, I think so. The problem is that the knowledge base is not there on which to proceed. And so we are having to build that now. So the first ones to go forward have to do most of the work. But, hopefully, they will be increased.

Mr. DOOLEY. And so you see that as an alternative? Mr. Olson, could you agree that, from my prospective as a grower, when I see the potential of having a 100-day cotton variety out there or a corn plant that would have increased tolerances to aphid mite, that sounds attractive and would reduce my pesticide usage.

Would the NRDC support that?

Mr. OLSON. Our opinion has been that much of the investment has been put into developing herbicide resistant plants so that some companies will get a larger market share by developing plants that are resistant to the herbicide and, therefore, more of the herbicide can be sold.

Mr. DOOLEY. Sure, we can isolate examples of that. But in the broader context, it sounds like something that you folks ought to be excited about if it is going to reduce the use of pesticides and herbicides.

Mr. OLSON. We think it is part of an overall use. There may be some use for that. But we don't want to consider it as a silver bullet.

Mr. DOOLEY. It may be an area that, as part of our final compromise, it could be a component of that final piece of legislation that could provide, again, another alternative that could help to build the solution to this problem.

Ms. HINKLE. Mr. Dooley, genetically modified substances was a part of the Charlie Rose new generation provision, as was semiochemicals, naturally occurring substances and biocontrols. It is not the process that should be a problem. It should be the product and any inherent harm that a particular product poses. But as we build a base on this, we should proceed so as not to make each new product go through all the hoops all over again. We must build on this knowledge base, which benefits development of genetically modified substances.

Mr. DOOLEY. One last comment, Mr. Chairman. And I thank you for the indulgence here.

There was also—and I think, Mr. Olson, you gave some attention to the issue of Federal preemption. I have to tell you that some real concerns that I have in California are that if we allow local government entities and even State entities, in some instances, to have the ability to have authority over the use of some pesticides, we create an opportunity for some real negative public health consequences. For example, in the case of the medfly, if the folks in Los Angeles County decided that they didn't want to allow the use of malathion to combat the medfly, the result would be having the entire California agricultural industry quarantined.

And this is the real apparent challenge that we face if we don't have some reasonable restrictions on the latitude that local governments have in placing their own restrictions. And, hopefully, there is some ground there that we can find on this issue too.

Mr. OLSON. I would like to respond just quickly. One point is that all politics are local, as you know; and we believe that a lot of these local issues should be resolved through the local political process. I think it is unlikely that a community is going to ban something that is going to bring economic devastation upon it.

Second, the commerce clause does prohibit any actions by local government or State government that interferes with interstate commerce. And we have seen that repeatedly in the hazardous waste field where local governments may take a protectionists attitude and the courts have said, no, you can't do that.

And third, the primary clause suggests that if a local government takes action that is contrary to what a Federal law requires, that also is superseded under the supremacy clause. So we believe that there are very few, if any, instances where a local government or State government has done something stupid. And if that does happen, there are built in protections that the courts can use as well as the local political process that can be used.

So we think that federally mandated preemption is not the way to go. And we would strongly oppose it.

Mr. STENHOLM. We thank all of you for your attention and your testimony today. We look forward to working with you in the days ahead. Thank you.

We will call the second panel, Mr. Vroom, Mr. Engel, Mr. Gullickson, Mr. Pflug, and Mr. Balek.

Call the first witness, Mr. Jay Vroom, president of National Agricultural Chemicals Association.

**STATEMENT OF JAY VROOM, PRESIDENT, NATIONAL
AGRICULTURAL CHEMICALS ASSOCIATION**

Mr. VROOM. Thank you, Mr. Chairman. We thank you for the opportunity to examine the all-important pesticide issues of registration and reregistration.

Without a solid foundation of these two features of our U.S. regulatory system, effective public policy, useful products for farmers and ranchers, and improvement in public perception are all impossible to achieve. NACA represents the companies that manufacture, sell, and distribute virtually all the crop protection materials used by American farmers. And as others will tell you on this panel, our members have experienced challenges and opportunities from registration and reregistration that parallel that on the act side.

My written statement discusses at length the complexities of registration. Before you, I have one example of a relatively new herbicide manufactured by one of our member companies. And the information that has already been alluded to by Mr. Feldman in the cardboard boxes before you on the floor, I think, very accurately illustrates, and perhaps understates the sheer magnitude of what the registration challenge represents to our industry and provides all of us a glimpse of how thorough the testing and approval process that we undergo before we bring a new product to the marketplace really is.

I would like to point out that the 11 boxes before you represent an investment by this company on the low end of research experience, approximately \$20 million.

Let me emphasize that I believe that there is room for improvement on all sides of the registration and reregistration process. Registrants can do a better job of listening to EPA requests. Agency policymakers can become more proficient in delivering early and accurate descriptions of study tests. I would like to point out that much progress has been achieved in improving the EPA registrant efficiency quotient.

Finally everybody else—media, environmental community, and the public—can be more constructive and supportive of the process rather than delighting in the constant rock throwing that we have seen in the past.

The product which I am describing to you here today is a member of the so-called sulfonated urea family. It represents a family of compounds first discovered in 1969. It wasn't until the early 1980's that the first of these compounds were brought to the marketplace, primarily for the wheat market in the Plains, Colorado, and Texas.

This family of compounds is very, very effective. And the particular example that I have here today—and all the registration data that was submitted to EPA represents something of a follow-on in the generation. Although the first compounds in the sulfonated ureas were registered by the EPA in the early 1980's, this particular derivative was discovered by Ciba-Geigy in 1981.

The company applied and received a permit for experimental use in 1987 and applied for full registration in 1988. Authorization for full registration and licensing was granted in 1990 from EPA.

Several hundred scientists at Ciba-Geigy were involved in developing and researching this product. We have counted in excess of 100 base studies in these boxes. Depending how you want to count—and we have already heard the use and misuse of statistics—there are maybe as many as 200 studies represented in these boxes.

If you count some of the follow-on study requests that EPA made it took approximately 8 years of study to bring this product on to the market in 1980—despite the fact that another company had already brought sulfonated urea similar in composition in the marketplace years before. They did studies in 40 different locations around the world on this particular compound, and in excess of \$20 million in research alone.

Dozens of EPA scientists were required to go through the mountain of data that you see before you until ultimately, in 1990, American corn farmers had this product available for postemergent weed treatment.

I might emphasize that the benefits of this product represents an evolution not only in terms of low dosage, highly active ingredient but because it is a postemergent compound. It represents a new ingredient in integrated pest management or IPM.

There are five small packets that I will show you. The company packages it in this box that will hold 5 larger packets or 25 water dissolvable packets. The total value of this to the farmer is \$750, and that will treat 50 acres to control very effectively a wide range of very important and threatening weeds.

The farmer will take the packets out wearing protective clothing, limiting his exposure to the compound with a gloved hand and drop the packet into the tank, instead of having to mix a large quantity out of a jug such as this, which is typical.

The packet dissolves and the packaging problems are vastly reduced. This company, and many others, have gone a long way in investing in research for better packaging as well as better products. This product is now effective in a very low dose rate in a range of half an ounce of active ingredient per acre, which displaces products that would require several pounds to have the same effect.

In the 11 boxes in front of you, there are a wide range of over 100 tests represented. For example, in box 322, there are eight different tests packaged inside that cardboard box. Residues in eggs and poultry; soil metabolism; acute LD-50 tests on bobwhite quail; nondietary studies on mallard ducklings and bobwhite quail; acute toxicity tests on sheeps head, minnows, clams, mice, and shrimp; hydrolysis, and photo degradation in water are among the few of the many studies that are before you.

I think this is recognized even by our opponents in the environmental community as being representative of the kind of new chemistry that the public is demanding and supporting.

To conclude, I would be happy to answer any questions that you have about this particular compound. I have examples of popcorn and field corn on top of the boxes to remind you that these are the commodities that we are trying to produce. And I think we need to remind ourselves, and the previous panel, that it isn't chemical

companies or farmers who are constituents but ultimately food consumers who are our constituents.

I would like to submit a copy of this paper to you for inclusion in the hearing record. It is a paper that was published by the Council on Agriculture, Science, and Technology in their January 1993 edition entitled "How Do We Test for Safety of Food?" It is authored by Dr. F.J. Francis of the University of Massachusetts at Amherst. I don't personally know this particular scientist, but I want to quote a section with regard to MTD that Mr. Smith and Mr. Dooley were pursuing earlier which may help clarify some of the points that are being made here.

It says that: The level of dosage is probably the most controversial with regard to testing a pesticide residues and establishes safety levels. "A standard bioassay is performed on both sexes of animals in the lab. Thus, with 50 animals in each group of rats, a total of 800 animals is required. Dose levels are usually the maximum tolerated dose, one-half of the MTD, and one-fourth of the MTD. The use of MTD has been criticized because it causes cell proliferation, mitogenesis, and rapidly dividing cells are more susceptible to mutations, mutagenesis. Mutating cells are more susceptible to the production of tumors or carcinogenesis. Critics have charged that the MTD is too high and in itself causes cancer, not the product in question."

That, effectively, is what most of the compounds are now triggered against with regard to the Delaney concerns that EPA has identified.

I thank you again for the opportunity to speak primarily about a very important fundamental issue which is registration and re-registration. And we look forward to your questions.

[The prepared statement of Mr. Vroom appears at the conclusion of the hearing.]

Mr. STENHOLM. Thank you.

Mr. Ralph Engel, president of Chemical Specialties Manufacturers Association.

STATEMENT OF RALPH ENGEL, PRESIDENT, CHEMICAL SPECIALTIES MANUFACTURERS ASSOCIATION

Mr. ENGEL. Good morning, Mr. Chairman. The CSMA has a membership of some 440 firms engaged in the manufacture, formulation, and sale of nonagricultural pesticides, including automotive chemicals, detergents and cleaning compounds, home, lawn, and garden pesticides, and a wide variety of pesticides for industrial and institutional use.

Mr. Chairman, the subcommittee is precisely on target in examining the EPA pesticide registration process. The Environmental Protection Agency is charged with the dual responsibility of protecting human health and the environment and registering pesticides for general use, restricted use, or both. The current system is not working, and it is time that the subcommittee exercise its oversight responsibility to see to it that the agency improves the administration of this program and is held accountable.

The consequences of a malfunctioning Federal registration program are far reaching. The registration program has become the single most burdensome process which EPA administers. It signifi-

cantly restricts the ability of manufacturers and formulators to enter the market and compete in the market by imposing unreasonable delays on applicants. Many of our member companies have been denied the opportunity to introduce identical products, me-too products, if you will, to compete with those already on the market, let alone to develop new active ingredients.

While we believe that reform of the registration process is essential, CSMA is not seeking changes that will compromise thorough scientific review or the public health. On the contrary, the current process is denying the availability of products with significant public health benefits.

CSMA believes that the EPA and the regulated community would immediately benefit from a statutory requirement that EPA contract with appropriate outside management personnel to conduct a thorough examination of the registration and reregistration process. The report should be completed promptly, perhaps within 9 months. It should inform the Congress as to how to improve the registration program's performance. Every company in this country practically does that on a routine basis, and I think it is important that we take an outside look at EPA as well.

In 1988, FIFRA amendments under section 3(c)(3)(B) created an expedited review for registration applications which are identical or substantially similar to a currently registered pesticide product. FIFRA now requires that the applicant receive notification from the agency as to whether or not the application is complete within 45 days and, subsequent to such determination, that these applications be approved or denied within 90 days.

This process is not working. And, thus, even the simple label changes and applications to register products, which are identical to others previously registered, can take over a year to complete. Congress created expedited review and specifically earmarked \$2 million to eliminate registration backlogs in 1988. Yet 5 years later, EPA is not utilizing this tool.

CSMA recommends that the subcommittee legislatively compel EPA to implement a procedure under which a failure by the agency to notify an applicant within 45 days would result in the application being deemed complete. A failure of EPA to render a registration decision within 90 days would result in the application's approval. This is not unique. It is being done under the TSCA program now.

The fate of antimicrobial products has been caught up in the morass because they are included in the definition of pesticides in FIFRA. These products have nonfood uses, and they are used in our hospital facilities and homes everyday. These provide benefits for maintaining the public health. For instance, in the aftermath of Hurricane Andrew, some of the most sought after products were bleach, disinfectants, and insect repellents. And I am pleased to say that our member companies sent truck loads of these products to that area to meet those needs.

One of the most compelling illustrations of the problem with the EPA registration system is that it has been a number of years since any antimicrobial product has been registered. One of our firms has had a pending application in the EPA system for nearly

7 years without a final decision. Changes in FIFRA are needed to be enacted to address the antimicrobial product area.

We believe that the subcommittee should separate and distinguish antimicrobials from other pesticides by establishing the Office of Antimicrobial Programs. The subcommittee could consider and develop a separate statutory definition for antimicrobials distinct from pesticides but, certainly, within FIFRA jurisdiction. With the establishment of this dedicated EPA function and separate statutory definition, registration applications could enter the system correctly and be handled by appropriate designated personnel. This would accelerate review within the agency and would permit more precise accountability and thus assist the subcommittee in its oversight function.

The 1988 FIFRA amendments imposed annual maintenance fees on all pesticide products and all pesticide active ingredients in order to pay for the program. The annual maintenance fees were to raise \$14 million per year over 9 years. EPA increased the basic fee for 1990 and 1991 but still fell short of collecting \$14 million. In its budget for fiscal year 1992, after much negotiation with CSMA and other industry groups, all represented at this table, as well as EPA, an agreement was reached on a package of FIFRA amendments.

Despite the fee agreement, early in 1992, EPA informed Congress and industry that the agency, over the next 6 years, would fall short of funds necessary to complete its reregistration activity. And by the way, that was less than 6 weeks after we reached the agreement that this was announced.

EPA, therefore, sought additional fees in its 1993 budget. That fee request was denied. But it is clear that the agency's intent is to seek new fee authority in its fiscal year 1994 budget.

This subcommittee and Congress should withhold granting any additional fee authority to EPA pending a thorough review of the reregistration and registration programs. Such a review must include an examination of funds collected and utilized in both programs thus far. It has become obvious that throwing more money at the agency isn't going to improve the productivity of the program.

During the debate on the 1988 FIFRA amendments, this committee considered a CSMA proposal that required the synchronization of data review between the States and EPA. While not including the provision in the 1988 amendments, the committee did assure the industry that it would reconsider this matter during the next FIFRA reauthorization.

The issue of data requirements and uniform standards of review and evaluation of data by EPA and the States continues to be critical for both active ingredient manufacturers and formulators of pesticides in obtaining registrations from EPA and with various States. We recognize the need to fill data gaps at the State and Federal level and are not suggesting that the State requirements be necessarily preempted by EPA decisions.

However, we urge that, as part of reregistration, the States and EPA coordinate and synchronize data requirements so that only one set of data needs to be generated within the same timeframe

and that the standards of review used by EPA and the States for examination and evaluation of new and existing data are the same.

I want to thank you, Mr. Chairman, together with the rest of the subcommittee, for recognizing the serious shortfalls of the registration process by holding these hearings. EPA must now be assisted by the subcommittee in achieving the fiscal management, statutory responsibility, and properly focused priorities to effectively and successfully implement the 1988 congressional mandate.

The program's immediately improved performance is important to the Congress, EPA, the environmental community, taxpayers, and CSMA members alike.

Thank you for your time, and I will be glad to respond to your questions if there are any later.

[The prepared statement of Mr. Engel appears at the conclusion of the hearing.]

Mr. STENHOLM. Thank you.

Mr. Gullickson.

Mr. HANSHAW. Good morning.

By way of introduction, the Chemical Producers and Distributors Association is a voluntary, nonprofit membership association consisting of about 100 member companies engaged in the manufacture, formulation, distribution, and sale of products used on food, feed, and fiber crops and for lawn, garden, and turf care.

With me to present testimony is Bill Gullickson, chairman of the board of CPDA and also president of the McLaughlin Gormley King Chemical Company in Minneapolis, Minnesota.

STATEMENT OF WILLIAM GULLICKSON, CHAIRMAN, CHEMICAL PRODUCERS AND DISTRIBUTORS ASSOCIATION, ACCOMPANIED BY HUNTER HANSHAW, MANAGER, REGULATORY AFFAIRS

Mr. GULLICKSON. I will tell you that the firm that I am the president of is not a law firm but is in the botanical extracts business.

I appear before the members of this House Subcommittee on Department Operations and Nutrition to discuss a number of pesticide issues of importance to our association.

Today, I would like to share my thoughts with the members of the subcommittee on several specific issues relating to the Delaney clause, to the EPA's registration and reregistration programs, as well as questions surrounding reregistration fees and minor use.

First, the Delaney clause and its impact on food safety. The zero-risk Delaney standard is simply unworkable for establishing reasonable risk evaluation. When Delaney was promulgated almost 35 years ago, the usual scientific testing standards were measured in, at best, parts per million. Scientific detection standards now measure in the parts per trillion, resulting in the detection of potential lab animal carcinogens which are found at levels that pose negligible threat to the public.

To avoid cancellation of numerous valuable pesticides and to ensure the safe and abundant food supply, section 409 of the FFDCA should be amended to reinstate the flexible concept of reasonable risk when setting permissible tolerances for pesticides in processed food.

We at CDPA strongly support H.R. 1627, the Food Quality Protection Act of 1993. It would create a single, negligible risk standard for toxins in raw commodities and processed food. The EPA would be responsible for defining negligible risk in light of evolving science, taking into account different routes of exposure to the pesticide and the sensitivity of population subgroups.

Now the EPA pesticide registration and reregistration programs and specifically the fast-track system, which is an oxymoron, for almost 5 years the EPA has been allegedly implementing the provisions of the 1988 FIFRA lite amendments but has not been able to clear the backlogs that exist in the registration division. This backlog especially affects fast-track products despite congressional authorization for up to \$2 million per year of reregistration maintenance fees to be used for implementation of fast-track.

As formulators and distributors of generic end-use products, this was the most important aspect of the registration process to our segment of the pesticide industry. The agency has not effectively spent the funds nor spent a proportional share of the agency's allocation to address this congressional mandate.

We at CPDA would like to offer the following suggestions. First, we believe that the resources within the expedited review program should be used to hire or assign an expedited review person for each of the 11 project managers so the applications can be reviewed in a timely manner.

Second, CPDA would like to see a notification system set up for identical me-too products patterned after section 5 of the TSCA. Under the rule, if EPA does not respond in 90 days, the me-too product can be marketed.

Third, the Administrator could establish a standard for me-too products and label changes and establish specific regulatory procedures. A substantially similar or identical product can be deemed to have been registered upon notification to the EPA by registered mail.

In the area of label changes, several different offices in the agency and special programs within EPA office of pesticide programs require, at different times, changes on the pesticide products label. Specific programs suggest specific needs to change the label, such as the endangered species program. The label improvement program seeks to improve the labels and make appropriate changes. Label changes may be requested from the air and water division of EPA to conform with the Clean Air and Clean Water Acts. No one part of the agency coordinates appropriate label changes. These various programs do not know what the other parts of the agency are doing about label changes.

CPDA would like to offer the following suggestions:

First, one office in OPP within the registration division, would coordinate all label changes from all programs, all product managers, and all divisions so that there is no confusion about the necessary changes needed to comply with the EPA's mandates.

Second, one date each year should be selected for all EPA mandated label changes. We suggest October 1 as the main date because it represents the end of the growing season and the beginning of the new fiscal year.

We applaud this subcommittee's efforts last May 17 when it included this label proposal in the en bloc amendment provision to H.R. 3742. We strongly urge your inclusion of this amendment in any FIFRA bill that is reported in the 103d Congress.

The registration cost and reregistration cost issues. During the past 3 years, the EPA has recalculated the cost of the reregistration program and each year has substantially redone its estimate from the 160 million figure to 120 million. The Agency has consistently revised these numbers downward. When the new numbers are released this spring, it will be important to get an accounting of where and how the moneys were spent in the first years of the program.

Before we spend \$20 million more, maybe we ought to find out what has been done with the money spent to date and where can we identify cost savings that might be able to be achieved by the agencies as well as efficiencies in the handling of these systems. Only then can we come up with an accurate cost of the reregistration program. We pledge our efforts to work with the Congress and to identify and correct this problem.

In the area of public health, CPDA strongly supports H.R. 1867, the Public Health Pesticides Protection Act of 1993 introduced in this Congress by Representatives Calvin Dooley and Wally Herger of California. The legislation ensures that EPA establish guidelines that take into consideration the need for and benefits of public health pesticides used to combat disease-carrying insects and pests.

In the area of minor use, CPDA supports the concept of the Minor Crop Pesticides Act of 1993, H.R. 967. We believe the mechanisms found in H.R. 967, such as time extensions, certain waivers, and use of surrogate data in conjunction with present data compensation provisions in FIFRA provide ample opportunity to support these chemicals through the reregistration process.

While we support the major provisions of H.R. 967, we are opposed to patent term restoration. We believe that the extension of patent term periods for exclusive use of data will not assist minor-use protection. If Congress selects to extend the patent term, the result would be an unfair and inequitable solution that would drive up the costs to farmers, ranchers, and pesticide end-users.

In conclusion, we at CPDA respectfully urge this subcommittee to hold additional hearings on related FIFRA issues and mark up the bill as soon as possible.

We strongly support H.R. 1627 for its treatment of Delaney as well as cancellation and suspension. We support H.R. 1627, the Dooley-Herger bill. And we urge your support for the yet-to-be-introduced bills by Congressmen Volkmer and Smith on preempting local jurisdictions from regulating the sale and use of pesticides, and Congressman Steve Gunderson's bill on synchronization and coordination of data between Federal and State agencies.

In addition, we support Chairman E (Kika) de la Garza's minor-use bill, H.R. 967, except for the provision on patent extension. And we strongly support fixing the registration and reregistration process so that products can be handled in an efficient, expedited manner.

We applaud this subcommittee on the work on these issues and look forward to working with you in the 103d Congress.

[The prepared statement of Mr. Gullickson appears at the conclusion of the hearing.]

Mr. STENHOLM. Dr. Pflug.

STATEMENT OF GERALD R. PFLUG, PRESIDENT, SOAP AND DETERGENT ASSOCIATION

Mr. PFLUG. Thank you, Mr. Chairman.

Mr. Chairman and members of the subcommittee, my name is Gerald R. Pflug, and I am president of the Soap and Detergent Association.

The SDA is a 139-member national trade association representing the formulators of soaps, detergents, and household cleaning products and those companies which supply ingredients to the detergent and cleaning products industry.

SDA's members include nationally prominent as well as less well known, small, often family-owned companies. Along with well known formulators of highly visible consumer products, SDA members also include the formulators of industrial and institutional products used in hospitals, nursing homes, hotels, restaurants, and public buildings. Over 90 percent of the cleaning products sold in the United States are made by SDA members.

The products of SDA members have a long history of contributing to the maintenance of public and personal health standards which are, unfortunately, often taken for granted in our country today. Clean clothing, bedding, cooking utensils, plates, silverware, kitchen and bathroom fixtures are, in fact, the broad base on which our exceptional standard of public health rests.

The SDA is here today because of its concerns for one of the most important contributors to our high cleanliness standards: antimicrobial and disinfectant cleaning products.

Under FIFRA, antimicrobial and disinfectant cleaning products are regulated as pesticides by the EPA because they are intended for preventing, destroying, or mitigating harmful microorganisms, viruses, and bacteria. Common, well-recognized examples of such products include certain brands of chlorine bleach, when such claims are made, Lysol Disinfectant cleaner, and Comet Cleanser. Less well known, although equally important, are the myriad commercial products used in business establishments, public accommodations, and public buildings.

I am here today on behalf of SDA's antimicrobial disinfectant products sector because this beneficial category of products faces a number of regulatory problems which we believe ought to be addressed through the reform of the FIFRA process.

The principal problems of concern are the following: The approval process for new, active ingredients needs improvement. No new active antimicrobial agents have been approved in 7 years.

The process for registering or reregistering products is so cumbersome and attenuated that such processing may require up to 2 years to complete.

The approval of simple label changes may take 9 months or more.

The consequence of these regulatory logjams has been to impede the development and introduction of additional safe and efficacious antimicrobial products in the marketplace.

We believe the underpinning for resolution of these regulatory problems already exists within FIFRA.

FIFRA section 25(a)(1) reads as follows:

"Regulations. The Administrator is authorized in accordance with the procedure described in paragraph (2) to prescribe regulations to carry out the provision of this subchapter. Such regulations shall take into account the differences in concept and usage between various classes of pesticides and differences in environmental risk and appropriate data for evaluating such risk between agricultural and nonagricultural pesticides."

If antimicrobial and disinfectant products, as a subset of non-agricultural products, were distinguished under FIFRA and provided a separate regulatory track, we believe that the approval process for these products would be facilitated.

Based on reports by our affected members, it seems that informal structures have already evolved within the EPA along the lines we are proposing. These informal arrangements have, however, proven inadequate to resolve the problems faced by the antimicrobial-disinfectant industry. Some increased degree of formalization appears to be required in order to effect the process efficiencies required.

Further, it seems to us that the establishment of a separate antimicrobial regulatory track would benefit the EPA as well as industry by clarifying standards and establishing an effective division of labor within FIFRA regulatory approval processes.

While I wish that I could offer you a comprehensive solution to the issues of our concern, I cannot do so today. I am pleased to tell you, however, that the SDA is currently working to develop a more concrete proposal for your consideration along with allied associations. Some of which are represented here today.

Mr. Chairman, and members of the committee, this concludes my formal remarks. The SDA appreciates the opportunity to be here today, and I would be pleased to answer any questions you might have.

Thank you.

[The prepared statement of Mr. Pflug appears at the conclusion of the hearing.]

Mr. STENHOLM. Thank you.

Mr. Balek.

STATEMENT OF WILLIAM C. BALEK, DIRECTOR, LEGISLATIVE AFFAIRS, INTERNATIONAL SANITARY SUPPLY ASSOCIATION

Mr. BALEK. Good afternoon.

My name is Bill Balek, and I am the director of legislative affairs for the International Sanitary Supply Association. We are a non-profit trade association comprised of over 4,000 members located across the Nation. The majority of these companies are considered small businesses. Over 60 percent of these companies have annual gross revenues of less than \$2 million and have 10 or less employees.

These companies manufacture and distribute a broad variety of institutional and industrial cleaning products including antimicrobial pesticide products such as disinfectants, sanitizers, and germicides which are governed by FIFRA. These products are used by hospitals, nursing homes, schools, food processing plants,

hotels, restaurants, and other institutional and industrial establishments to maintain sanitary and healthful conditions.

We appreciate this opportunity to testify, and we thank you, Chairman Stenholm, and the rest of the subcommittee members, for conducting this hearing.

Our entire statement addresses a number of important questions, but I will limit my oral statement to expedited registration, maintenance fees, H.R. 1867, as well as labeling issues. Our complete written statement has been submitted for the record.

In regard to expedited registrations, we encourage Congress to explore options to ensure that the expedited registration provisions of the 1988 amendments to FIFRA, known as fast-track registration, are properly implemented. Fast-track registration required EPA to expedite the processing of products that are identical or substantially similar to existing pesticide products and for which no scientific review of data is required.

As described earlier, under this expedited process, EPA is required to approve or deny the completed application for registration within 90 days.

In fact, it is rare that this 90-day deadline is met by EPA. Our membership has pointed out numerous instances where it has taken 6 months to well over 1 year to process their fast-track registration. This delay creates an anticompetitive situation, especially for a small business whose, perhaps, only advantage may be the speed with which they bring a product to market. More importantly, this situation denies the public the benefit of new and improved products.

The ISSA was an ardent supporter of the fast-track amendment during the 1988 reauthorization of FIFRA. Our view was based on the fact that many registrations were not processed in a timely manner. In 1988, the EPA had a tremendous backlog of me-too registrations, when, in fact, these could have been processed in a fraction of the time; but because of priorities, these registrations were assigned a very low priority.

Today, approximately 5 years after its enactment, fast-track registrations are still not processed in an expeditious manner. The 90-day deadline is certainly the exception, and not the rule. We encourage you to direct EPA to improve its management of the registration process. We ask that EPA be required to designate specific personnel in each product manager's registration team to work on fast-track registration.

We also support the notification system that was described earlier and was supported by the CSMA and CPDA. We ask that you somehow encourage EPA to relook at their registration process and to fix what doesn't work.

In regard to maintenance fees, ISSA opposes an increase in pesticide maintenance fees or a provision that would extend EPA's authority to levy such fees. As part of the 1988 FIFRA amendments, Congress provided EPA with the authority to raise \$14 million a year in registration fees over the course of the 9-year reregistration program, in addition to the one-time fee on active ingredients.

We opposed the imposition of fees at that time because we believed it would result in a significant reduction in the number of registered products. In fact, there was an approximate 50 percent

reduction in overall product registration. That decline in product registrations resulted in a shortfall of the annual goal of \$14 million, which sparked another round of increases of fees. The adjustments to the maintenance fees ultimately resulted in reaching the statutory goal.

However, EPA is once again seeking additional revenues to finance their programs. We oppose increases in pesticide maintenance fees or any provision that would extend EPA's authority to levy such fees. Moreover, we oppose such fee provisions that do not take into account small business considerations or low-volume products.

Since 1988, annual maintenance fees have increased from \$425 to \$1,350, and the fee limitations, otherwise known as CAPS, have almost tripled. These costs have placed a substantial burden on small formulators of antimicrobial pesticide products, and have caused industry to cancel numerous registrations, drastically altering product mix and marketing strategies. We believe that further increases in maintenance fees would only prove to be even more burdensome to small business.

ISSA also supports the Public Health Pesticides Protection Act, H.R. 1867, because it recognizes the important role that antimicrobials and other pesticides play in maintaining the safe and sanitary conditions in our society. H.R. 1867 was introduced to provide recognition and relief for pesticides registered for public health purposes. The legislation specifically would extend consideration and protection to pesticide products used to maintain good mosquito and other vector programs.

But more importantly from our perspective, H.R. 1867 would extend the same special treatment to certain disinfectants, sanitizers, germicides, and other similar products. We support H.R. 1867 because it recognizes the importance of these products in maintaining safe and healthful conditions in our society. These products, however, experience unreasonable regulatory burdens, whether they be substantial fees or elongated delays in the processing of registration. Often they are lumped together in the risk/benefit analysis and treated as agricultural products might be.

We believe that these burdens threaten to keep a number of the products out of the market because it is not economically feasible to maintain their EPA registration. Consequently, products essential to the maintenance of safe and healthful conditions will be dropped from the market unless some relief is provided. We believe H.R. 1867 provides that relief.

Among other things, H.R. 1867 would exempt pesticides classified as public health pesticides from the reregistration and annual maintenance fees. It would also create a separate class of pesticide registration for these pesticides, the public health pesticides, with a risk/benefit analysis separate and distinct from that utilized for agricultural pesticides.

H.R. 1867 would also expedite the registration of products necessary for public health protection. For these reasons we encourage the support of H.R. 1867.

I would like to touch on the issue of labeling and the problems it presents for us. ISSA strongly encourages Congress to adopt legislation that would require the agency to coordinate the many dif-

ferent label changes required by the EPA. Presently several different offices and programs within EPA require modifications to existing pesticide product labels. Unfortunately, there is no internal coordination of these various label changes.

EPA of course at various times requires numerous modifications to existing labels. The changes might reflect a new active ingredient, an inert or a slightly different use. Other changes are made to incorporate a new set of directions or warnings about use or specific health and safety instructions. At other times, EPA may require a label to be modified to include new instructions for proper disposal.

In addition, specific programs within the agency address specific changes to labeling contents. For example, the labeling improvement program requires various modifications to label contents. In essence, many different offices and programs within the agency require registrants to alter their labels.

However, there is no one mechanism in place through which EPA is able to coordinate these various label changes. Consequently, companies may modify their label to address one program's requirements, only to find several months later that they must once again alter their label to address another EPA requirement. This situation is especially problematic for our membership who formulate and distribute private label products.

For example, one formulator holds over 100 product registrations that are each sold under 20 to 30 different private labels. Consequently, one label change required by the agency results in the printing of thousands of new labels, sometimes only to find that another program or Department requires additional changes only months later. This lack of coordination often results in the company discarding thousands of dollars in labels because they are made obsolete by another EPA directive.

We therefore recommend that several changes be made in the EPA's labeling policy to avoid these complications. First, we suggest that EPA establish one office within the Agency that would be responsible for coordinating all label changes required by the various offices and divisions within EPA.

Second, we recommend that EPA select one date a year in which all label modifications are required. We believe that these suggestions should provide EPA with sufficient flexibility to respond to a crisis or other situation that would require immediate change to be made in a label. We believe that if adopted these suggestions would be consistent with EPA's need to monitor and revise labeling, as well as ease the burden placed upon industry.

Last, just very briefly, we would also like to lend our support to the coordination of data requirements between EPA and the various States. We also would like to lend our support to the establishment of a separate office within EPA's Office of Pesticide Programs, set up specifically to handle antimicrobial registrations.

I thank the subcommittee and I am prepared to answer any questions that might arise.

[The prepared statement of Mr. Balek appears at the conclusion of the hearing.]

Mr. STENHOLM. Thank you very much. Mr. Allard.

Mr. ALLARD. Mr. Chairman, right now I don't have any questions. I am sorry I had to miss some of your testimony.

Mr. STENHOLM. A couple of you have suggested that EPA's use of current funding should be investigated, perhaps I am using the wrong word, but should be looked at prior to any additional funding. By that, are you making a suggestion that there has been perhaps a misuse of funding?

Mr. ENGEL. Mr. Chairman, speaking for CSMA, we are not making any such accusation, but as we sit here today, both you representing Congress, and I representing the affected industry, really know where the funds have gone in this process. And I think if we are going to get anywhere in this registration, reregistration process, these programs have to be looked at in-depth. The funds have already been collected; we need to know where they have been spent. I suggested in my testimony that we have a third party look at the process and make recommendations.

I believe that from our position, that is necessary at this time because it is neither getting fixed internally, nor are we, both industry or Congress, fixing it by compelling them to do so. And it would be our judgment that a third party management group go into that agency and review all segments of registration and reregistration and recommend to you changes that should be made.

Mr. VROOM. Mr. Chairman, I would like to respond also on behalf of members of NACA. We agree with much of what Mr. Engel has just said. We observe that the adjustments we made in compromise legislation a couple of years ago have resulted in substantial increases in the maintenance fee income. It went from a low in the first year of \$7.5 million, leveled off the next 2 years at \$11.5 million, and then jumped to \$15.8 million and then last year \$17.1 million, which is about \$3 million above what the original annualized projections called for in the 1988 amendments.

The other reason I think that it is worthwhile for this committee and Congress to look closely at this area is that it is not just industry fees, user fees. The original commitment made in the 1988 amendments was for Congress to appropriate a dollar for every user-fee dollar. So there are public funds also in question here. And ultimately, we all are more concerned about getting the job done, meeting the deadlines and reestablishing more public confidence.

And the only way to get there is to make sure that we are being efficient in terms of the expenditure, not only the user-fee dollars, but also those appropriated funds as well. And I think that our members are willing to consider paying a little more money if we can see where the money is going and how we get to the goal line with a reasonable and efficient expenditure of funds, whatever the number is.

Mr. STENHOLM. I should have prefaced that question by stating that this subcommittee is going to be very involved in the reorganization of USDA, an in-depth look from the top to the bottom, from the bottom to the top, in the manner in which USDA is serving producers and consumers in the United States. This is our responsibility. I would hope and expect the same will occur with EPA, particularly since there is a suggestion that it be made a cabinet position.

I would hope that this in-depth review from bottom to top will occur and intend to be a part of that because the two working together are going to be extremely important, that we have a working relationship between not only EPA, USDA, but FDA and perhaps several other entities.

This is one of the in-depth analysis that we are going to have to go through.

I also was struck by one statement that was made in the first panel today concerning whether or not information being requested, proper information, is useful information, is helpful information. And I think we have ample evidence in many areas of government in which questions being asked are totally irrelevant to the problem that we are looking at.

I suspect that if we look through these boxes in front of us today, that almost everyone, including those responsible for the creation of whatever it was that caused these boxes to be filled up, would say yes, there is some very, if not unnecessary, certainly not very helpful information requests that have been made. I say that in accepting the fact that quite often those of us around this dais here are responsible, not the bureaucrats, but those of us here are responsible for putting something into the law that someone interprets requesting this kind of information in order to protect someone.

And that is something we really have to be diligent on as we proceed to the goal that we have before us today and for the remainder of this year. Along that line I want to ask you each a question. I assume you each heard a portion of the previous panel. There were four groups represented.

Have you in the last month, 3 months, 6 months, had any conversation with any of those individuals at that table pursuing what perhaps might be commonly called today a middle ground? Did anybody?

Mr. VROOM. Mr. Chairman, I would say that we at NACA have not in that timeframe. We have had discussions off and on but not within the last 6 months.

Mr. ENGEL. We would respond for CSMA the same way, Mr. Chairman.

Mr. GULLICKSON. We at CPDA to my knowledge have not had any, Mr. Chairman.

Mr. PFLUG. At SDA the same, we have not.

Mr. STENHOLM. I would assume that the same answer would be that there has been no communications with the new administration as yet along the same lines, would be my assumption.

Mr. VROOM. That is not correct.

Mr. STENHOLM. Not correct?

Mr. VROOM. There has been one meeting that we at NACA participated in, along with the other leaders of the food chain coalition that have been responsible in helping support and introduce and obtain cosponsors for the Lehman-Bliley-Rowland alternative on food safety. That meeting occurred with representatives of EPA, USDA, FDA, and the White House a week ago yesterday.

Mr. ENGEL. Mr. Chairman, on behalf of CSMA we, too, have met with the administration on a number of these issues. But still there are not all the key people at the Agency to deal with as yet.

Mr. GULLICKSON. At CPDA that has been our situation, Mr. Chairman. We have had meetings with EPA personnel, but at this point there are a lot of policy personnel missing from the administration side, so we have dealt with interim folks, but we are waiting kind of for the administration to put some people in the offices.

Mr. STENHOLM. I should have asked the question a little bit differently. At the time and at the moment that the new administration has all of their proper people in place, you will be anxiously soliciting their views, ideas, cooperation, and ear, as we begin to work on FIFRA reauthorization? I assume the answer to that would be questionable.

Mr. PFLUG. Yes.

Mr. STENHOLM. Mr. Dooley.

Mr. DOOLEY. Thank you, Mr. Chairman. And I apologize to some of the panelists, I had to step out for a minute. But I would like to just get back to the issue of the MTD, the maximum tolerated dosages, and expand upon that to the differences between the registration process in the United States versus other developed countries in the world. Is this MTD process used extensively throughout the world?

Mr. VROOM. There are other countries that use high dose testing but at significantly lower levels. OECD testing guidelines provide for minimally toxic doses compared to the U.S. standard of extremely high doses—which result in sick, stressed animals and lead to false positives. No other countries pursue the extremely high dose testing we have designed here through the regulatory process at EPA for pesticide testing, using maximum tolerated dose.

As I referenced in the University of Massachusetts paper, maximum high dose stresses normal metabolic function and causes breakdowns in biological processes of the tissue. Biologically the MTD creates the opportunity for carcinogenic tumors to occur that otherwise would not occur at virtually any other dose level.

So there is a significant difference in the way the United States versus the way other developed countries approach the testing and dose levels. And I believe it is putting American agriculture at a disadvantage as we see the implementation of the Delaney lawsuit unfold at EPA.

Mr. DOOLEY. I have another question in terms of that. Because I think that there was comment, even agreement among the prior panel, that this is not a perfect system by any means, and what I would be interested in, if maybe there isn't a better system out there that somebody else is using. I don't mind this data being developed, I think it is probably useful even using the maximum total dosage, but the problem is that when you extrapolate, the curve that totally disregards what the other two groups, the control group plus the other two test groups showed you don't factor that into the curve.

I guess there was a comment that the dose—that they agree with the dose response curve, I think the person from the NRDC did that. But if you in fact have an instance of a material at the MTD being carcinogenic, is that there really isn't a dose response curve; is that correct?

Mr. ENGEL. That is correct.

Mr. VROOM. That wouldn't be an automatic assumption, no.

Mr. GULLICKSON. Could I ask something, Congressman, to this whole MTD issue that you touched on this morning which from my own company's point of view is an actual circumstance? Wherein we did a bioassay, 18-month bioassay, which is about \$500,000. And at the end of the day we didn't satisfy EPA's criteria for meeting the MTD.

We didn't have a toxic response sufficient to the agency. There was some weight loss, but statistically it seemed to be not significant enough for them to the point where they are mandating that we spend another \$500,000 to go out and run another one at a higher dosage.

Now, the range finding works suggested the dosages that we selected were, in fact, toxic. But in the case of this particular compound, it turns out that whatever process the mouse uses for metabolizing the material overcame whatever its initial indications to toxicity were and by the end of 18 months these mice were pretty damn healthy, excuse my French, but I mean they were, which you might extrapolate to suggest our chemical was a life prolonger, although I wouldn't want to sit here and tell you that.

Mr. DOOLEY. What I would be interested in from any of you that have access to this type of information is if you think there is a better way. One person brought up the issue of tissue analysis and some other type of techniques out there. Just because we have been using this process for some time doesn't mean we have to be continually wedded to that.

And that would be information that I would certainly be most interested in receiving.

Mr. STENHOLM. Mr. Allard.

Mr. ALLARD. Thank you, Mr. Chairman. I do have some concerns I might bring up. The previous panel had talked about the fact that the maximum tolerated dose was a way of shortening the investigation period, it was actually to the benefit of industry. Can you respond to that? Do you feel that if we just went with a public health safety standard, in other words we check out a product to make sure that it doesn't create a risk to public health, that that is really what you can do and you can do the research parameters to meet that as a practical standard? Anybody want to respond to that?

Mr. ENGEL. I think I understand what you are saying. Let me take a shot at it. It certainly costs less and takes a shorter period of time to take less animals and dose them to the maximum tolerated dose level, than it would to take several thousand animals over generations and follow it through that process. That is how the tox data development process has occurred.

I guess all of us have been involved in the discussions or have seen discussions about whether we should be extrapolating data obtained on a mouse to man. Then we get into interpretations of the data itself. And certainly, no, we don't have an exact science here.

It is most difficult to deal with and I think that has caused some of the problems; because people interpret data differently and people are concerned about interpreting data and making decisions from time to time. So there isn't a better system that I have seen, but this is certainly not a good one, to be honest about it.

Mr. ALLARD. Mr. Chairman, I will proceed on a little more if that is OK. Mr. Engel, you also talked in your testimony about one of your member companies that waited nearly 7 years for registration decision on a single-use product. Can you provide this subcommittee with any further details on this matter?

Mr. ENGEL. Sure can. And still are waiting, by the way. The company is Dow, and it filed for registration of a product called DTEA, an antimicrobial product, back in March of 1987. It is a product that would be used in cooling towers to kill microbes, viruses, or other like organisms. And understand being used in a cooling tower, it is in a closed system, so the exposure to both human health and the environment is very minimal.

In January of 1988, EPA told Dow that it expected to complete the registration process in little over a year, in fact they gave them the number of days, 375 days. During the more than 6 years of confused and frustrating dealings with the EPA registration program since, two examples really best illustrate the institutional caution and uncertainty that characterizes the registration program.

First in 1988, the agency requested that Dow undertake two subchronic aquatic studies. These studies have never been previously required of any other registrant using the same kind of product. And so they did complete the fish studies and the invertebrate life cycle studies, only to be told later why did you do that, we didn't need those any way.

And it is that kind of thing that has drawn this process out for 7 years until finally the most recent chapter in this unfortunate tale occurred in April of this year when the—excuse me, when the Director of the Registration Division, who joined the division fairly recently, agreed with the company that the agency has all the data it needs to make the final decision. Now we can sit back and pray that they do make a decision.

And by the way, that is not a single tale of woe. That can be multiplied many hundreds of times.

Mr. ALLARD. Obviously we have some concerns there about efficiency of the process. Do you have some specific suggestions on how we can best examine the management of the EPA registration program?

Mr. ENGEL. Congressman, you probably had stepped out at the time, but I have suggested to the subcommittee and to the chairman that it is time for a third party review. And I don't mean a Government review. I am talking about bringing in, under contract, management personnel to review the registration and reregistration program in its entirety and see how best to handle this program and how efficiently to handle this program.

And I think it is important that we take that next step because it is going to save all of us and particularly the consumer, money in the long run.

Mr. ALLARD. Thank you, Mr. Chairman.

Mr. STENHOLM. Mr. Engel, I think your suggestion is an excellent one and having had experience in the past not with Government but with producer moneys being looked at by an outside disinterested party, I found it was one of the better things that we did and got an incorporated role earlier on. I think yours is an excellent idea and we will make that suggestion further known.

Dr. Pflug, since you are new to this debate, just for the record, what do your members in your organization produce?

Mr. PFLUG. We are the manufacturers of the soap and detergent products throughout the United States. Our members consist of people like Procter & Gamble, Colgate, Lever, raw material suppliers like du Pont, Monsanto, Witco. And our membership represents well over 90 percent of the soap and detergent products sold in the United States, both to the consumer as well as to institutions.

Mr. STENHOLM. The products that your members manufacture are subjected to the same registration and reregistration requirements that we are talking about across the gamut?

Mr. PFLUG. If indeed they make antimicrobial disinfectant claims for their products, they are classified as pesticides under the current FIFRA regulations.

Mr. STENHOLM. Now, one of our most difficult questions that we are going to have to resolve, politically difficult questions, and that is the Delaney clause, the zero tolerance, which again I think we finally got an agreement with the first panel that that is physically impossible, technically impossible, to assure our Nation's consumers that there will be zero carcinogen present in our water, our food, whatever.

And I think the educational process is going to be one that we have to pursue with great diligence. The press that reports on these meetings and others need to go more in-depth as to just exactly what we are talking about, rather than the concerns that we all have when someone suggests that we have a cancer-causing agent in our food. More and more people need to understand that 98 percent of the known carcinogen, at least according to the best scientific evidence available, God made all by himself.

It is the 2 percent that we are concerned about and no one, certainly not this chairman or any member of this committee, wants to do anything that will increase the risk to anyone. In doing that, and as we start pursuing the legislation necessary, we intend to bring the public health sector into these debates.

We have not had those charged with the public health as involved in these issues as we would like. We have too many opinions based on different interpretations and I certainly would like to see more of the public health sector involved and certainly intend as chairman of this subcommittee to utilize their testimony and their opinions as we try to come up with the proper solutions that we have before us. The questions—the budget limitations that we have are very real. It means we are going to have to spend our dollars much more wisely than we have in the past.

If there is a message coming through from the general public about what they want their Government to do, they want us to do a better job but they want it done with less money. And that is certainly something that we intend to pursue, but not to the detriment of human health. That has to be prevalent in all of our minds, but by the same token, management is extremely critical. It is in the businesses that you represent.

Management is also important to Government and I think you will see this begin to be more prevalent in our decisionmaking process.

I have no other questions at this time. We thank you, gentlemen, for your testimony today. We look forward, too, to working with you. And I would seriously suggest that each of you in your own way and your own time make contact with the previous panel to begin to pursue what Mr. Gunderson and Mr. Dooley said earlier, and start looking for some of the middle ground that is going to be necessary to move forward with this legislation, because we are going to move forward.

And the sooner that you can do that on your own, individually, it is your time and place to begin to find those areas, the more helpful you can be to this subcommittee in achieving the goal that the first panel and this panel and the next panel all want to see done.

Thank you for being here.

We call panel 3. Deputy Secretary Rominger; Mr. Victor Kimm, Acting Assistant Administrator, EPA. Secretary Rominger, we welcome you to your first appearance before this subcommittee. Welcome.

STATEMENT OF RICHARD ROMINGER, DEPUTY SECRETARY, U.S. DEPARTMENT OF AGRICULTURE

Mr. ROMINGER. Thank you, Mr. Chairman, members of the subcommittee. I very much appreciate the invitation to present the department's views on pesticide registration and reregistration, including the consequences of strict enforcement of the Delaney clause, minor-use pesticide concerns, and reduced-risk pesticides and how all these relate to the American consumer and American agriculture.

Pesticide policy is a major focus of the administration. We fully recognize the need for action. Over recent weeks, there have been numerous discussions between the Department, the Food and Drug Administration, and the Environmental Protection Agency. We are continuing to meet with the goal of refining an administration position on pesticide regulation and related issues.

The Department has been and will continue to be a full participant in these discussions. I believe we can agree that the Federal Government must regain the confidence of the public, that it's protecting American consumers and the environment from problems linked to the use of pesticide chemicals. The loss of important food use pesticides can result in heightened risk of disease-causing organisms in food, food price increases, adverse effects on food quality and its acceptability, and reduction in the availability of nutritional food choices.

To make the best decisions, we need to make revisions in two statutes that control pesticide use, the Federal Insecticide, Fungicide, and Rodenticide Act, FIFRA, and the Federal Food, Drug, and Cosmetic Act. Changes to these laws must consider the following five objectives.

One, public health protection. Harmful exposure of the public to pesticides in the food supply must be prevented.

Two, restore and build public confidence, ensure that the food supply for Americans continues to be safe.

Three, provide appropriate oversight of pesticides and pesticide use, prevent the use of pesticides with unreasonable risks and develop safe alternatives.

Four, streamline pesticide regulation so that pesticide producers and users can understand and comply with pesticide and food safety laws and still have the necessary tools to produce and deliver safe food to the American consumer.

And five, to protect the environment.

We commend you and the committee for holding this hearing and hope that with the collective efforts and wisdom of the Congress, the executive branch, consumers, the agricultural production sector, public interest groups and the agrichemical industry, that we will be able to achieve workable reform to the laws regulating pesticides and food safety. The responsible use of pesticides by food producers and distributors has played an important role in providing a safe, available, abundant, and affordable food supply for the American consumer and for part of the world. Agriculturalists, many of whom can also claim to be environmentalists, have used pesticides as an effective tool to provide food and have enabled our domestic food system to be easily managed.

We also recognize that there must be continuous improvement to that food delivery system, acknowledging that there is a shared responsibility for consuming and producing food. Those shared responsibilities must also blend with the shared goals of public health and environmental protection to reaffirm that our food supply is safe.

The registration and reregistration processes are incredibly important to both the shared responsibilities and the shared goals of pesticide regulation. These regulatory processes are extremely complex and increasingly costly to the agricultural sector, to the regulatory community, and to the consumer. These processes demand that we make the best regulatory decisions possible, using state-of-the-art science and good public policy.

Mr. Chairman, the sciences of risk assessment, toxicology, and analytical chemistry have changed much faster than our understanding of pesticide risk. Medical and public health sciences are constantly evolving. EPA must have the flexibility to adopt these changes and use them in risk assessment and risk management.

EPA must also have the ability and the resources to act promptly and effectively based on the best scientific information to deal more creditably with problem chemicals and thereby help restore public confidence in pesticide regulation. USDA strongly supports a streamlined approach in a cancellation process of a pesticide chemical for EPA.

We also support early, frequent, and meaningful consultations in all cancellation activities, and support appropriate interaction with EPA, FDA, USDA, consumers, producers, and the agrichemical industry in such matters.

As stated by the National Academy of Sciences in "Regulating Pesticides in Food, the Delaney Paradox," central to pesticide regulation is the reregistration process and this process is linked with the setting of tolerances in food. Tolerance setting has proven to be more complex and troublesome since the ninth circuit court's decision in *Les v. Riley*. The court ruled in this case that under the

Delaney clause, EPA has no discretion to establish pesticide tolerances that allow pesticide residues to be present in processed foods at levels greater than the pesticide tolerances allowed in the raw agricultural commodities, if the pesticide induces cancer in animals, regardless of how small the risk.

Applying the court's decision, EPA has revoked five emergency exemptions it had granted previously, and denied 16 other emergency requests for special pesticide usage, even though EPA, FDA, and USDA continue to believe that the pesticides affected by the court decision pose only a negligible risk to public health. Tolerances must now be denied for some agricultural products that would otherwise be permitted under FIFRA.

The alternative to the Delaney standard would be a more practical standard of negligible risk. Mr. Chairman, we commend you and appreciate your interest in addressing minor-use pesticides. Vegetables, fruits, nuts, trees, ornamentals, herbs, and turf grass are often referred to as minor crops, even though those crops account for about 40 percent of the dollar value of all agricultural production. There are also a number of minor uses on major crops that require special pest control treatment.

A recent publication was entitled "Pesticides, Minor Uses, Major Issues," but we hear from growers that it is more like "minor uses, major problem". We are continually made aware of food production problems stemming from minor-use pesticide products being dropped or canceled. Tied to the registration and reregistration process, agrichemical companies cannot justify costs of producing data or conducting studies for a pesticide that will never recapture these costs.

I am sure you are aware of the many pesticide registrations that have already been canceled, and we do not have a problem with many of those cancellations of pesticides that were seldom if ever used. But as a result of the current reregistration efforts, many more minor use products are not being supported by the pesticide manufacturers. As the number of products diminishes for minor uses, the remaining pesticides are used more, and pest resistance to those products increases.

Scientists agree that pest resistance is best managed through a variety of products with diverse mechanisms for control of the pests. Increased use of a single product, or products with a similar control mechanism, can lead to a serious situation where there are not products available that are effective or the amounts used must be increasingly large and thus present greater human and environmental exposures.

USDA supports expedited registration of biological pest control agents by EPA. USDA has facilitated the Minor Use Working Group since 1990 to discuss and recommend new approaches for reaching registration decisions impacting upon minor crops. The members of this group include USDA, EPA, chemical manufacturers and associations, and growers. An information system has been developed to rapidly and efficiently disseminate information from manufacturers to growers concerning minor-use products to be canceled.

This more timely information helps growers plan their production strategy and manage their crop more effectively. USDA has

approached the minor-use problem through support of the IR-4 program. The IR-4 project, headquartered at Rutgers University, is a national program established in 1963 for the clearance of chemical pesticides for minor and specialty crops and animal drugs for minor uses. The IR-4 project coordinates directly with the Federal regulatory agencies, especially EPA and FDA, industry, and crop producers.

IR-4 has been expanded to include pest control activities in the biological pesticide area, a new direction where researchers and growers are optimistic for new pest control mechanisms. In 1989, USDA initiated a multiagency effort to collect and analyze pesticide use and residue data regarding actual levels in food, beginning with fresh fruits and vegetables. This program is providing EPA with data that is important to reregistration efforts. USDA continues to be supportive of the development of products that pose fewer risks to humans and the environment.

USDA research, both chemical and nonchemical, has as its objective more efficient and effective pest controls without great risks. USDA supports the registration of pesticides that can be used effectively with less risk, and supports any waiver of data requirements that EPA deems appropriate along that product's registration journey.

The Department will work together with EPA and FDA to effectuate appropriate changes in our existing pesticide regulations that will enhance food safety, yet preserve the viability of the agricultural industry.

Mr. Chairman, this concludes my statement. I will be glad to respond to any questions the committee may have.

[The prepared statement of Mr. Rominger appears at the conclusion of the hearing.]

Mr. STENHOLM. Thank you very much. Next we will hear from Mr. Victor Kimm, Acting Assistant Administrator, Office of Prevention, Pesticides and Toxic Substances, EPA.

STATEMENT OF VICTOR J. KIMM, ACTING ASSISTANT ADMINISTRATOR, OFFICE OF PREVENTION, PESTICIDES, AND TOXIC SUBSTANCES, U.S. ENVIRONMENTAL PROTECTION AGENCY

Mr. KIMM. Thank you. Good afternoon, Mr. Chairman. We have a rather lengthy testimony, since it has been a while since we have been up. I would like to submit that for the record.

Mr. STENHOLM. Without objection, the entire statement will be made a part of the record and we will appreciate a summary.

Mr. KIMM. And hopefully a brief summary. To begin with, the new administration is pursuing both legislative and administrative changes to enhance consumer protection from pesticides. EPA would like to ensure that our regulatory decisions are sound, timely, can be made, administered and enforced in a consistent manner to protect public health and the environment, while providing an abundant and affordable food supply.

As Secretary Rominger has indicated, EPA is part of a task force with FDA and USDA and the White House to look carefully at legislative proposals to deal with a variety of issues facing the program, including Delaney, but essentially looking toward a package

which will be, when read in total, more protective of public health and the environment than our existing framework.

The new administration is also deeply committed to working with Congress and all interested parties as we try to find a formula which will break the gridlock that has prevented legislation in this area from moving in the last few years. We are all looking forward to our joint efforts to make that happen.

Specifically, the testimony today deals with registration and re-registration, and the ongoing licensing functions of the program. As it relates to registration, I think the facts that I would like to call to your attention is just the immensity of the task. In a typical year in its registration activity, we received applications for 20 new active ingredients, 220 petitions for tolerances, 900 applications for pesticides that resemble products already on the markets, the famous me-toos, 45 new uses of old pesticides, 5,300 other amendments to existing product registrations, a 115 experimental-use products, and 350 requests for section 18 emergency exemptions.

The practical consequence of that, is just to keep the backlogs from growing, we need to make on average 27 regulatory decisions a day, and that is a sizeable task. Within that universe, we are particularly both conscious of and trying to respond to the growth in biological pesticides, which are a growing portion of the new active ingredients that we are licensing.

These pesticides are by their very nature different from the traditional chemical pesticides. They require innovative approaches to testing and risk assessment and in some instances that results in reduced data requirements, enabling us to move the process more quickly. In some instances, it raises different issues which require different testing, but these are significant.

We believe that this class of pesticides are inherently safer than the traditional persistent and toxic chemicals that they replace, and we are pleased to see the marketplace moving in this direction in recent years. Another part of the registration program which the committee has expressed some interest in deals with fast-track amendments and me-too registrations.

The fast-track amendments are label changes requested by registrants that can be made within a registration division, they don't require independent new scientific judgments. The me-too group of registrations are new applications for registrations of an active ingredient which is already approved, so that these are primarily transactions.

They are very important to the regulated community, and they constitute a significant portion of our workload. However, as we are beginning to look at tightening resources, they provide us an area in which they do not offer as much risk reduction potential as some of the other things that we can do with the available resources and that is the source of some management choices that we have made and will continue to make in the future.

In essence, we had been moving to significantly reduce the backlog in these categories. As you can see from the charts attached to my testimony, last year faced with about a 30 percent cut in our contracts resources, we have made the decision, a risk-based decision, to not continue to invest more heavily, to further reduce those backlogs which are being carried at about their present rates.

That is one of the issues which you all may choose to focus upon. Another area that we are actively pursuing are activities related to the registration of reduced-risk pesticides. We published a Federal notice on this last year, held a workshop that was widely attended, and have taken the first steps in trying to implement these policies.

Simply stated, with these policies we would like to encourage the registration of reduced risk, that is safer chemicals and other forms of pest control mechanisms, and reduce the dependence on the classical persistent and toxic. In our most recent pronouncement in this area, we've announced both short-term activities, namely a notice to registrants explaining what kind of data we would like them to give us if they would like to qualify for accelerated reviews based on the argument that the proposed product is inherently safer than the things that it might replace.

We have also announced a commitment to a long-term strategy to try to develop specific criteria that would be principally scientific to sort out more risky from less risky pesticides, to streamline the regulatory process itself, and then finally to look at changes we might make in the way we do business that would encourage the marketplace to move in this direction.

Some of our classical policies, for example resisting the desires of pesticide registrants to make comparative claims, may perhaps stand in the way of moving in the direction the marketplace is already moving in and these are policy areas in which we have solicited comments and will be trying to address in the immediate future.

Finally, in the registration area, we are trying to exercise the provisions of section 25B, that is to look for classes of pesticides which are inherently safe or a minimal risk like cedar chips, and to take them formally out of the regulated universe, again to reduce the workload, to focus our attention where we think it is most needed, and to try to avoid situations where we are spending significant time looking at products that are inherently of very small if any risk at all.

In the reregistration area, this has been a top priority of the program for a number of years. We think that since here we are taking the pesticides that were registered long ago and bringing their data sets up to current standards, that there are significant potential for risk reduction and therefore are very important. I would also like to reinforce the point in my testimony, that as this process proceeds, as soon as we learn of a risk, that we had not previously understood, we are moving to work with the registrants, typically to reduce exposure in order to mitigate those risks as soon as they are detected.

And that means in practice that we don't have to complete the registration process to deal with new perceptions of risks. We are dealing with those as soon as they are developed and there are a number of those listed on page 12 of my testimony, but these are instances in which we and the registrant became aware of a problem and then moved to deal with that problem long before the reregistration process is completed in full.

In any rate, we have now completed 31 reregistration eligibility documents, the famous RED's. Those cases cover some 47 active in-

redients and deal with about 2,500 products. At the RED stage, we have made decisions about the active ingredient and its inherent risks and benefits and perhaps things that need to be done, for example if it poses a threat to aquatic circumstances, those kinds of considerations are identified at that part in the process.

The next step is to deal with the individual products derived from those active ingredients, which typically involves toxicological testing of the particular formulation, which leads to decisions on whatever changes may be needed on the label. For example, the 31 RED's that have been concluded involve about 2,500 products and of those some 33 products have totally completed the drill, reregistered products, some 600 products have been voluntarily canceled for one reason or the other, and the remainder, something like 1,700 or 1,800 products, are in the process of testing, collecting the data, having that reviewed by the Agency.

Here again, this turns out to be an enormous task. I believe that the accomplishments that we have made thus far in the last 5 years lay the basis for significant progress in the future. We have in fact now a process which we have run all the way through. We believe we understand where the particular strengths and weaknesses of that process lie.

We have taken a number of focused efforts on the management side of that process to look at things like study rejection rates that have a significant impact on our ability ultimately to finish the process. As indicated in the attachments to the testimony, our current estimate continues to be that the 1997 date is in fact unattainable, that we will by present estimates expect to complete about 55 percent of the cases by the 1997 deadline, and those RED's would involve about 86 percent of the high-volume agricultural pesticides that are of most concern.

The remainder of that process, assuming the existing level of resources continue and that the outside support through fees terminates in 1997 described in present statute, would not see the rest of the reregistration eligibility documents completed until the year 2004.

I would close with the note that we continue to believe that if, in fact, the difference between current levels of funding and that which we could apply to the availability of the new studies—we believe with the addition of the \$20 million increase, the 1997 deadline completion would increase from something like 55 percent to 60 or 65 percent. But those would all be high volume pesticides with significant potential for public health improvements.

We are looking toward NAS's children's study which should be released at the end of the month. In that study, the Academy was asked to look at the basic question: Are children more or less sensitive than adults to pesticide residues; and second, the adequacy for a change in the way the system does risk control assessments. And we expect to receive that at the end of the month, and we will move quickly to deal with the recommendations coming forth from the Academy.

A second area deals with the Delaney implementation. In response to that, in February, we released a list of the universe of potentially impacted pesticide-crop combinations. At the same time, we released a list that identified pesticides that appeared to meet

the Delaney clause "induce cancer" standard and discusses many of the policies that deal with who does, in fact, need a 409 tolerance. We have completed the public comment period and are now beginning to work our way through a mountain of comments that we have received on this issue.

And, in addition, as Secretary Rominger indicated, on May 7, we made the first actual application of the court decision. That was to go back to rescind five section 18's that had been granted and to reject another 16 that were pending.

We believe in FDA that this is a logical extension of the court's determination, and we do not think, in the short run, that we have much flexibility. The next activity will be a Federal Register notice in the next few weeks to deal with three active ingredients on seven crops which were covered by the court action and we had not addressed thus far.

Finally, we are looking toward fall of this year, perhaps the late fall, in which the Agency will have considered the reassessment of the policies that relate to applying Delaney and then apply those decisions against this larger universe of 32 active ingredients and propose whatever changes come out of those issues. These are significant issues.

I am pleased to answer any of your questions. And thank you for your attention.

[The prepared statement of Mr. Kimm appears at the conclusion of the hearing.]

Mr. STENHOLM. Thank you very much, Mr. Kimm.

I am always delighted when the chairman of the full committee can be with us. Chairman de la Garza, we would recognize you for any remarks or questions that you may have for these witnesses.

REMARKS OF HON. E (KIKI) de la GARZA, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

The CHAIRMAN. Thank you. Thank you very much, Mr. Chairman.

Let me add my welcome to Secretary Rominger and Acting Assistant Administrator Kimm. We are very happy that you are here to help us in this endeavor. Our instructions to the subcommittee and to the chairman are that we take an in-depth look at the spectrum of pesticide registration and reregistration issues. And we heard this morning from various witnesses, whose testimony I have read, and there will be further hearings on it.

First, let me say that I think there is a major need in this area of our concern that, just as you two gentlemen sit here today, that we do that everyday—that EPA and USDA work together. Outside the parameters of legislative action there must be an operating procedure where you—and your respective agencies—are in constant contact and liaison. One can't operate without the other. Hopefully, just as we see you here today, we will see the Administrator and the Secretary working together in this area.

Second, after reading some of the testimony from earlier this morning, I don't know if we can really move agriculture entirely away from chemical pesticides tools and toward alternatives that can effectively deal with all of the other problems of agriculture. I know that there are some who insist that this can be done. I don't

know if it can be done or not. But I do think it is our responsibility that we try and minimize the use of anything that might have harmful potential in the environment, including the human element.

At the same time, we can't abandon the farmer who needs the necessary tools. So I would suggest that both of you gentlemen carry back to your agencies that there be some positive interaction—again outside of what we are speaking about here today, with the users and the producers to look for ways to see if we can do that.

I know that for the farmer it is a dilemma, as both of you gentlemen know, because pesticide tools are a factor in his productivity. Without using the tools, his productivity declines. I would hope that more research in that area could be done by the EPA and also by the USDA. We need to know to what extent we can reduce the need for pesticides, through integrated pest management, which is a broad phrase and other alternatives. We can work together to find ways to minimize the use.

In the end, the decision has to hinge on the impact on health and safety of the environment and of both human and animal inhabitants of this planet of ours. I would hope that with a common purpose, we can come toward—I don't know that you could have a total solution—but a workable solution that you minimize risk to farmworkers, to farmers, to the residents in the area, and to the environment. Through technology and the expertise of the producers, I think we can develop new tools and practices that are less harmful but yet effective for the farmers.

We have a dilemma on our hands with the Delaney clause, with the minor-use issue. There are twists to these issues that most do not realize. I know of a case right now where a young scientist has developed a product that is farmer friendly, farmworker friendly, environmental friendly, and effective; but he doesn't have the resources to register the product. So that is part of my interest in the so-called minor use.

I know there was testimony this morning that minor crop producers use more pesticides per acre and all of that. I don't know if this is true or not. But our interest is that if there is a pesticide product that can be helpful and can be proven safe to use that it not be negated because of the limited resources of the individual or individuals bringing that product forward.

The time element, I would like to say is totally unacceptable. It is totally unacceptable. We don't have enough budget resources, and you don't have the personnel or the resources. Yet we must put our best foot forward and go ahead knowing that we have a problem. And every nation in the world has a problem in relation to this area.

So my main point is, just as you sit here today, hopefully that this will be what your two agencies do every day. That we reach out to the user, that we reach out to the producers, and that you work together to give us the necessary information. All so that we might hopefully have legislation commensurate with legislation that is within the art of the possible. What is possible that day, that hour, that very minute. And if we do that, I think we would have taken a very good step forward.

Mr. Chairman, you and Mr. Smith will be major players in this endeavor; and we will work with you.

Mr. STENHOLM. Thank you, Mr. Chairman.

Mr. Smith.

Mr. SMITH. On that note, gentlemen, does this administration and do you two support the de la Garza minor-use bill?

Mr. ROMINGER. Mr. Smith, we have looked at bills—

Mr. SMITH. Careful. He is here now.

Mr. ROMINGER. We realize that there are going to be a great number of bills introduced. And we are looking at all of them. And we support solving the minor-use problem.

Mr. SMITH. Well, you must have been a halfback; you went around the end pretty swiftly there.

Mr. Kimm.

Mr. KIMM. I couldn't top that. As I said in my summary, I think that the new administration has not taken a specific position on any of the emerging issues. That is the business that we are about.

But I would share with the chairman that, by my lights, at least, there have been more high level and very constructive discussions between and among the agencies on these difficult issues in the last few months than perhaps in the last few years.

So in terms of the agencies coming together and trying to deal with these difficult decisions, I think we are making significant progress.

Mr. SMITH. But let me ask you a more serious question. Do you anticipate taking a position—it is important that you do—on this bill or any other position?

When will you have a position that you can share with this subcommittee to help us formulate, as Chairman de la Garza suggested, to help us formulate a final disposition of this issue?

Mr. ROMINGER. We are continuing those interagency meetings.

Mr. SMITH. No. I asked when you might have. Give me a time-frame.

Mr. ROMINGER. I can't give you an exact day, because this afternoon we are listening to another segment of the industry. We have listened to consumers and environmentalists, the industry, and the food processors. We are just about to complete that process. And then I would think that within a few weeks we should have an administration position on the whole universe of the pesticide registration, reregistration, Delaney clause.

Mr. SMITH. Before September?

Mr. ROMINGER. Yes, before September 1.

Mr. SMITH. Mr. Kimm.

Mr. KIMM. I would hope that we could move that quickly, yes.

Mr. ROMINGER. Our target is to have something before Labor Day.

Mr. SMITH. Mr. Kimm, you have been at the EPA for more than 20 years. How do we avoid the gridlock of \$20 million and 10 years to get us a product that everybody agrees is beneficial to all segments, the farmers, consumers, and the producers of the chemical?

How do we get to a point where we don't drive people out of the business of research that are productive and can be productive in this whole program?

How do we avoid this mess in front of you?

Mr. KIMM. I think part of the problem that we are facing in re-registration is the fact that there were never resources to begin the task until 1988. And so with one fell swoop we are trying to deal with this gigantic universe of old chemicals that were, at the time, tested against the standards that were prevalent when they were administered.

As we got into the five-step process that you put in the statute, we discovered that the stage in which the registrant went back and looked at data and said we think these studies are OK and these studies need to be done, that turned out to be an extremely costly scientific adventure as our scientists went through and agreed in some instances and disagreed in others.

That process is really coming to a closure. By the end of the year, we should have all the data call-ins out. That will enable us to apply the scientific expertise to review the studies that are pouring into the Agency at a rate of 200 a month. So I think that we have worked our way through the process. But I think the bottom line of your question is: How did this task get to be so immense; and why is it taking so long?

At the end of it, we should get ourselves on a routine schedule to upgrade pesticides on some more frequent basis. And it is the enormity of the task that we are into, rather than any other specific cost, that is making it time consuming.

Mr. SMITH. My question is: Why does it take 200 studies to finally get that product?

Mr. KIMM. On an individual active ingredient, it can be as much as 200 studies. That is what it takes with contemporary scientific questions to look at health effects, the ecological effects, the chemistry as the chemical may breakdown.

Mr. SMITH. There is no shortcut to this? There is no sense that says we have looked at it, it is complete?

I understand peer review, but 200 studies is ridiculous.

Mr. KIMM. That is the total universe that you might need on a new one. In most of the reregistration cases, it is some fraction of that, depending on how old the chemical is. I think there is some debate that those are the issues that need to be addressed, more so in some cases than in other cases. But that is what it takes to categorize a new chemical that is coming on the market to address the questions that we try to address.

Mr. SMITH. So your answer is that there is nothing that can be done about this?

Mr. KIMM. I don't think there is any simple paring away of those studies that could be done without raising significant questions that were not addressed.

If anything, science is probably going in the opposite direction. In 5 years from now, there will be more testing because we will be ready to address more toxicological end points. I think that is something that is likely to be discussed in the National Academy of Sciences study.

As the science develops, it raises more questions, and it takes more testing to answer those questions.

Mr. SMITH. Your scientists use MTD, I understand.

Mr. KIMM. I'm sorry. Could you repeat the question?

Mr. SMITH. Your scientists depend upon the MTD?

Mr. KIMM. The MTD is a part of the current testing for chronic effects; yes, sir.

Mr. SMITH. And the National Academy of Sciences says that isn't reliable?

Mr. KIMM. I read the National Academy of Sciences' report to say that it is probably the best tool available, although it has some limitations. I think that is a live issue in the community.

Mr. SMITH. I read it in the record this morning. You weren't here. I understand.

Are you suggesting that your scientists ought not to find a better measure than one the National Academy of Sciences says is unreliable?

Mr. KIMM. It is a major scientific issue involving the academy and us. We have a workshop planned later this year to look at that. But that is kind of the way science is. That it develops overtime and you have a certain set of ways of looking at problems and then people get to debating, and it changes overtime.

And from a regulatory or risk management perspective, we are stuck with dealing with science as it is. And we have to make decisions.

Mr. SMITH. Thank you.

The CHAIRMAN. Can I ask unanimous consent to allow the gentleman 30 seconds?

Mr. SMITH. Certainly.

The CHAIRMAN. I appreciate very much the gentleman's interest in my legislation. But the last thing I am concerned about is whose name is on the legislation or whether it is endorsed or not as one specific bill. The thrust must be at some sort of solution to the problem.

I appreciate very much your kindness, but whether it's the de la Garza bill or any other bill, we just want to get a solution. And as much as I appreciate it, whether it has my name or not is of very minor importance.

I thank the gentleman for being my friend.

Mr. SMITH. Mr. Chairman, I am delighted you are here. And I wanted to ask that question, because you see I am proud of your bill, even though you may not be.

The CHAIRMAN. I am proud of the bill too. It is just that the name is not the important factor.

Mr. STENHOLM. Mr. Dooley.

Mr. DOOLEY. I wanted to bring to the attention of my colleagues on the panel that Secretary Rominger, when he was director in California, provided leadership to allow the industry to incorporate pesticide management and regulations that have gone a long ways to instill confidence among the consumers. And it really works. And he really has a great deal of expertise in this area.

And what I wanted to touch on was the process that the administration has put together on the reform of the Delaney legislation.

And, Mr. Kimm, in your testimony, you say they set up a group that includes USDA, EPA, and the whole group. Is this what I was to understand, that the timeframe for this group coming up with a proposal is Labor Day?

Mr. KIMM. The quick answer is, yes. But I qualify that by saying we have not announced a specific schedule.

There are a lot of issues coming together. But it is the hope that by that time, and perhaps sooner, we will put together an administration position. Since we are just starting to deal with the issues, it is hard to project how long it is going to take us.

Mr. DOOLEY. And did I understand your testimony correctly that the EPA's position is that the decision dealing with Delaney in the ninth circuit court, is bad policy? Is that correct?

Mr. KIMM. Simply stated, yes. The Delaney amendment with the zero-risk for carcinogens presents a whole set of dislocations that we don't think are risk based. And we would prefer, as a matter of policy, to move on from the zero-risk approach to the negligible-risk approach as recommended by the National Academy of Sciences. And just about everybody who has looked at this issue.

Mr. DOOLEY. And Mr. Rominger, you state that, too, the alternative Delaney standard would be the negligible risk. We have two main agencies that adopt the concept of the negligible risk. So I assume that is the direction we are moving in.

Mr. ROMINGER. That is the direction we would like to move, yes. We think that science has passed up the Delaney clause and that we need to move on to something that is more realistic.

Mr. DOOLEY. Getting back to the point that Mr. Smith touched on—and we spent a lot of time on it today, and I think the reason for that is that it plays such a critical part in all the registration and the tolerances that are developed—and that is the MTD.

Does the EPA have a group of people within the Agency who are currently trying to develop a better methodology for determining the real risk of a product being carcinogenic?

Mr. KIMM. There are ongoing efforts addressed at those issues inside the Agency, some of them inside the Office of Pesticide Programs where we have a fairly vigorous and well-staffed health effects division, some of it within our Office of Research and Development, some of it in related Federal agencies that crisscross on these issues.

So the answer to your question is, yes, there is an ongoing effort to look at this.

We are also involved in an international workshop on the question of feeding doses. It is a big question, but it is not going to be resolved very quickly or simply.

In the meantime, we will continue to use the test protocols that we have established because until we make a change, the data that we are looking at comes off the protocols as they exist. So it is an ongoing scientific issue.

And, as I say, even with the academy study, it was far from—the academy said on the one hand, but on the other hand it is probably the best available technique that we have with us. It probably needs some additional study in the future, as I read that report.

Mr. DOOLEY. I guess, you know what a lot of our concern is, and even when we touch on the chairman's minor-use bill, is that a lot of the problems with lack of alternative products to be used for minor crops also goes back to this MTD.

When you establish a risk curve on it or response curve which is so high which then impacts the number of crops that then can be registered because of the allowable intake and that you effectively exclude the number of crops that then that particular prod-

uct can be registered for, and I really question whether or not, even if we streamline the minor-use registration process, if we don't eventually get to some more realistic appraisal of what the real increase in incidence of cancer is through a form of our testing protocols, that we really won't ever be able to address the minor-use problem that we currently face.

Mr. KIMM. The protocols that we use for cancer testing have been developed over almost two decades and involve a significant scientific review of almost all aspects of those testing programs. The heart of the matter is that you can test a limited number of animals. It is important to test them at very high doses to see if anything is going on.

The debate gets into at what point the high doses are so high that they induce other adverse effects that mask the significance of the chemical. But the notion of testing animals at high doses, in other words, to predict what the risk to human populations at low doses would be is fundamental to the science of toxicology and has been with us for at least two decades and had been fairly thoroughly studied. It isn't a matter of, gee, if you changed the doses, the effects would go away. It goes to depending on the test doses and the effects that you see how you project human risks associated with those chemicals.

And while these tools are far from perfect, they are the best tools that we presently have. And we run the regulatory programs based on mainstream thinking in the scientific community and these disciplines.

Mr. DOOLEY. The protocols which EPA uses for their MTD, how widespread are they? Are they adopted throughout the world in other developed countries?

I mean, is this the standard that France uses? England? Japan?

Mr. KIMM. There are some differences depending on where you are. But that approach to establishing the high dose levels for chronic exposure studies have been common practice in the United States since MTD adapted them about 10 years ago. We have been using them.

Some other people do, and some don't.

Mr. DOOLEY. Does Japan use them?

Mr. KIMM. I am not sure about Japan.

Mr. DOOLEY. And France?

Mr. KIMM. I believe the European Community has a slightly different approach.

Mr. STENHOLM. Mr. Allard.

Mr. ALLARD. Thank you, Mr. Chairman.

Mr. Rominger, I understand there is a lot of reorganization, staffing going on over at the USDA; and I guess the question that I have is: Are you going to be the one that is the lead policy official on pesticides? Or will it be somebody else?

Mr. ROMINGER. At the present time I am taking the lead on this area. We hope to have additional staff people in this area available and on board within a month or two. But I would expect that I will be still involved.

Mr. ALLARD. I hope that you and the new Secretary of Agriculture, Mr. Espy, will be prepared to take an active stand on this.

And I hope that you will really work hard on making sure that there is balance in that discussion.

If I could have your commitment on that, it would make a lot of us feel better on the committee.

Mr. ROMINGER. We certainly intend to represent the agricultural viewpoint.

Mr. ALLARD. Mr. Kimm, I get concerned about reports I have on our reregistration fees. It seems like you have come in and asked for more dollars for reregistration fees, and then every time we get down the road a little ways, there just doesn't seem to be enough and things don't seem to be progressing very fast in getting through the reregistration process.

And I am wondering if there has been any accounting of the reregistration fees recently in the EPA?

Mr. KIMM. We provided to the Congress in March, a breakdown of the sum of the revenues that we had received. And it covered both the one-time reregistration fee and the annual maintenance fees. The reregistration fees were lower than what everybody thought they were going to be because so many decided not to pursue reregistration. The maintenance fees is an area where there is a recap that allows us to collect \$14 million a year which was envisioned in the originally funding package.

I think, as I tried to explain in the testimony, this is a very complicated, large process involving a tremendous number of transactions; and I think we have been through the process; and we have made significant management improvements. And if you look at the schedules attached to the testimony, you will see that we are expecting to significantly improve the rate at which we are able to make these reregistration eligibility lists.

Mr. ALLARD. About 2,200 to 2,300 products had to go through reregistration; is that right?

Mr. KIMM. Products? 20,000.

Mr. ALLARD. 20,000 to 23,000.

And how many of those have been taken care of now?

Mr. KIMM. As I explained, only the first 40 or so, 35 products.

Mr. ALLARD. Only 35 or 40 out of the entire 20,000?

Mr. KIMM. The reregistration eligibility decision, that is the point where we make the risk benefit balance on behalf of the active ingredients. Those 33 active ingredients are incorporated in 2,500 products.

Only a few have finished that process because after the reregistration decision you have to test each product formulation for acute toxicity and eye and skin effect.

Mr. ALLARD. And how many employees do you have working on that?

Mr. KIMM. Some discussion here—about 350 working on reregistration. They are associated directly with reregistration in the science divisions that support that activity.

Mr. ALLARD. About 350 employees. And you have only approved 40 or 45 over that period of time? That's less than one product per employee.

Mr. KIMM. As I tried to explain, I think that is a poor—it is like counting the cabooses in a long process of trains, some of which are long and complicated and some of which are small.

None of us are happy with the progress to date. We would all like to see it accelerated. The agency is operating in a fishbowl in terms of where we are in that process. We have had internal management improvements and workshops involving outside participants, and we are running this project as well as we can from a public health perspective and environmental protection perspective.

We don't wait until the end of the registration process to deal with what are the most troubling phenomenons, that is, you take a chemical that has been on the market for 20 years and you run it through the testing and you discover a new problem that you didn't know about. When those are identified, we have, as policy—and have in policy—moved to limit exposure to these chemicals.

Mr. ALLARD. I assume that the EPA has kept detailed records on the appropriation shortfalls that have contributed to your problems now; is that correct?

Mr. KIMM. We can reconstruct, absolutely. The expenditures are accounted for to the nickel. The appropriations process is a public business, so we can relay those figures.

Mr. ALLARD. Can you forward those to this subcommittee?

Mr. KIMM. We can and will.

Mr. ALLARD. I would be interested in them.

Mr. KIMM. You may find that the report in March was an effort to go back and look and say this is how much money came in, and here is how it was divided up between the various tasks from science reviews to automated data systems.

Mr. ALLARD. So this one will be a detailed report so that we can identify the products that dropped out?

Mr. KIMM. We will have that in your office first thing in the morning.

[The information follows:]

February 3, 1993

EPA'S USE OF REREGISTRATION RESOURCES -- FY 1989-1992

The Environmental Protection Agency (EPA) was mandated by Congress to regulate the use of pesticides and to balance the risks and benefits posed by pesticide use. The agency regulates the use of pesticides through its Office of Pesticide Programs (OPP), within the Office of Prevention, Pesticides and Toxic Substances (OPPTS). OPP is a matrix organization consisting of seven divisions and a staff office. Over the past four years, OPP has spent a total of \$136.2 million on the accelerated reregistration program. Attachment 1 shows a distribution by function of where the funds were used, and attachment 2 summarizes the accomplishments of the program through 1992. OPP uses both appropriated and revolving funds in accomplishing its mission.

Of the total funds spent on the pesticides reregistration program, \$69.6 million went for salaries and expenses to support in-house OPP staff. The reregistration process is part of the broader pesticide program mission to serve the nation by safeguarding public health and the environment from risks posed by pesticides. The regulation of pesticides comes under two statutes - the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA). FIFRA gives EPA the authority and responsibility for registering pesticides for specified uses and the reregistration of existing pesticides that were registered prior to November 1, 1984. Pesticide regulatory decisions are based primarily on EPA's evaluation of the test data provided by applicants.

The reregistration process is conducted through reviews of groupings of similar active ingredients called cases. There are five (5) major phases of reregistration:

- o Phase 1 - Listing of Active Ingredients. EPA had to publish lists of active ingredients and asked registrants whether they intended to seek reregistration. This was completed in 1989: 1153 active ingredients from 611 cases were initially listed as subject to reregistration.
- o Phase 2 - Declaration of Intent and Identification of Studies. Registrants had to notify EPA of their intent to reregister and to identify missing studies. This was completed in 1990.
- o Phase 3 - Summarization of Studies. Registrants had to submit required existing studies. This was completed in 1991.
- o Phase 4 - EPA Review and Data Call-Ins (DCIs). EPA has to review the studies, identify and "call-in" missing studies by issuing a DCI. A "DCI" is a request to a pesticide registrant for scientific data to assist the Agency in determining the pesticide's eligibility for reregistration. 283 DCIs were issued through 1992.

- o Phase 5 - Reregistration Decisions. EPA must review all studies and issues a Reregistration Eligibility Document (RED) for the active ingredient(s). A "RED" is a determination by the Agency whether products containing a pesticide active ingredient are eligible for reregistration. The registrant complies with the RED by submitting product specific data and new labels. On the basis of its review, EPA reregisters or cancels the product. Pesticide products are reregistered, based on a RED eligibility determination, a process designed to ensure that it has met all label requirements. This normally takes 14 to 20 months after issuance of the RED. As of June, 1992, for List A, 6587 studies were reviewed out of 11,700 received. We expect to receive another 1200 studies. Through 1992, OPP issued 28 REDs, reregistered 41 products, canceled 165 products, and suspended 308 for not responding to REDs.

\$16.8 million in extramural funds were paid to contractors to review scientific studies submitted by registrants in support of pesticide registrations. The types of studies examined range from minor product chemistry data reviews to complex multi-year oncological studies. The results of these studies and subsequent reviews form the basis for a set of actions required in the REDs. These required actions impact one or more of the three risk reduction measures (dietary exposure, non-dietary exposure, and environmental fate and ecological effects).

In order to process all the data required by the accelerated reregistration effort, \$14.9 million were spent on a local area network, basic ADP operations, and numerous specialized information systems (see Attachment 3). These systems provide support for the following reregistration phases and functions: List A Inventory; List A DCIs; Phase II -- Lists B, C, and D; Phase III -- Lists B, C, and D; Phase IV -- Lists B, C, and D; Reregistration and Maintenance Fees; On-going DCI Management; REDs; and Product-level Reregistration.

\$9.3 million in extramural funds were used in the following areas to supplement in-house reregistration staff: AARP Support; Special Review and Reregistration Division support; Communications/Outreach: Universities/IAGs/Research Groups for determining chronic effects of pesticides, risk assessment methodologies, assessment of toxicological data, and other research functions; word processing support; and other pesticide reregistration support projects.

From 1989-1992, \$9.0 million were used by the following other Agency offices in support of pesticide reregistration (see Attachment 4): Office of Compliance Monitoring (\$5.7M), Office of Administration and Resources Management (\$1.6M), Office of Water (\$1.0M), Office of Enforcement (\$0.5M), and Office of General Counsel (\$0.1M). Totals do not add due to rounding. Starting in 1993, OPP will be the only office using revolving funds.

Standard overhead expenses totaling \$6.4 million went to the Office of Administration and Resources Management for agency facilities support.

\$7.3 million were spent to purchase personal computers (PCs) and related software; and to install, upgrade, and maintain Local Area Network (LAN) systems (see Attachment 4). The number of personal computers has grown in OPP from 125 PCs for 570 staff in 1988 to 805 PCs for 803 staff in 1992.

\$1.6 million were used for space moves (\$0.3 million) and purchasing furniture and other equipment (\$1.3 million) needed to support additional staff hired to perform reregistration functions.

\$1.3 million in extramural funds were used to support the processing of fast track amendments and old chemical reviews. The funds were used to hire AARP employees through the Senior Environmental Employees (SEE) program. These AARP employees are located in OPP's Registration Division and perform front end processing and other functions in support of fast track registration work. Through 1992, OPP completed 3568 fast track old chemical registrations and 10,466 amended registration reviews.

02/03/93

EPA'S USE OF REREGISTRATION RESOURCES -- FY 1989-1992
(\$millions)

Function	Appropriated Funds	Revolving Funds	Total
OPP Personnel Costs	46.0	23.6	69.6
Science Reviews/DCIs	7.4	9.4	16.8
Information Mgmt Sys	8.0	6.9	14.9
Other OPP Extramural	2.1	7.2	9.3
Other Offices' (non-OPP)	0.0	9.0	9.0
Agency Facilities Support	0.0	6.4	6.4
Local Area Network	0.3	5.0	5.3
Personal Computers	0.6	1.4	2.0
Space Moves and Furniture	0.0	1.6	1.6
Fast Track Processing (E/M)	0.3	1.0	1.3
Total	64.7	71.5	136.2

Summary of Accomplishments under FIFRA '88

- 1) Completed 283 Comprehensive Data Requirements in Data Call-Ins (DCIs),
- 2) Completed 28 Reregistration Eligibility Documents (REDs) or "other appropriate regulatory action,"
- 3) Completed 206 Product Specific Reregistration actions,
- 4) Completed 3,568 "Fast-track" Old Chemicals, and
- 5) Completed 10,466 "Fast-track" Amended Registrations.

OPP Computer Systems Supporting Heregistration

[illegible]

BREAKOUT OF OTHER OFFICES USE OF REREGISTRATION RESOURCES
 (\$millions)

1.	OCM --	\$5.7 (personnel costs: \$4.0; contracts: \$1.7)
2.	* OARM --	\$1.6 (personnel costs: \$1.6)
3.	OW --	\$1.0 (personnel costs: \$0.3; contracts: \$0.7)
4.	OE --	\$0.5 (personnel costs: \$0.5)
5.	OGC --	\$0.1 (personnel costs: \$0.1)

	Total	\$9.0 (personnel costs: \$6.6; contracts: \$2.4)

* (additional \$6.3 went to facilities support)

Note: Total does not add due to rounding.

Mr. ALLARD. Thank you, Mr. Chairman.

Mr. STENHOLM. Mr. Rominger, you mentioned on page 7 of your testimony in 1989, USDA initiated a multiagency effort to collect and analyze pesticide use and residue data regarding actual levels in food. This program is providing EPA the data that is important to reregistration efforts.

Can you share with us either briefly now or for the record what the results of those studies and effort have been?

Mr. ROMINGER. We have been collecting that data, and I believe we are about to release the data for the first half of 1992, which was the last that has been completed. So we will have that available, yes.

Mr. STENHOLM. What has it shown?

Mr. ROMINGER. Do we have the details?

Mr. STENHOLM. If you could furnish it for the record.

[The information follows:]

U.S. DEPARTMENT OF AGRICULTURE

PESTICIDE DATA PROGRAM*A PROGRESS REPORT FROM 1/91 - 3/92***MARCH 1992**

Public concern has grown over the past few years about the effects of agricultural pesticides on human health and environmental quality. Chemical residues on domestic and imported fruit and vegetables have been of particular interest.

Recognizing the need to improve the quality and quantity of information available on chemical residues, the Administration proposed the Pesticide Data Program (PDP) as part of USDA's fiscal year 1991 budget. Funding was approved by Congress in January 1991. The program was funded at almost \$17 million both for FY 1991 and FY 1992, and has a proposed funding of \$21 million for FY 1993.

PDP, which complements President Bush's 1989 Food Safety Program, was designed to provide actual residue and use data to help form the basis for conducting realistic risk assessments and setting pesticide tolerances. In addition, the program assists the Environmental Protection Agency (EPA) in addressing pesticide reregistration issues and removing troublesome pesticides from the market in a timely and effective manner. The program provides a data base for government agencies to use in responding more quickly and effectively to food safety issues.

PDP coordination is multi-departmental with planning, policy, and procedural efforts coordinated among USDA, the Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA). USDA has signed a Memorandum of Understanding on the PDP with EPA and is clearing it with FDA.

- EPA**
- . Provides USDA with registered pesticide and commodity pairs for data collection;
 - . Receives residue data from USDA, FDA, States, and private sources to support pesticide reregistration and special review decisions;
 - . Receives pesticide usage data from USDA, States, and other sources; and
 - . Receives food consumption data from USDA.
- USDA**
- . Collects data on agricultural chemical usage;
 - . Collects pesticide residue data on fresh fruit and vegetables through cooperative efforts with six participating States;

- . Provides EPA with actual pesticide residue information on fresh fruit and vegetables to be used in risk assessment studies for reregistration and special review;
- . Supplements FDA's monitoring activities in fruit and vegetables based on EPA-established tolerances or FDA administrative guidelines;
- . Produces residue and usage data for EPA, FDA, and the public; and
- . Provides EPA and FDA consumption data on foods and commodities.

- FDA**
- . Shares residue data-recording information and commodity coding systems, and commodity preparation information with USDA;
 - . Collects residue data to enforce EPA-established tolerances and FDA administrative guidelines for fruit, vegetables, and other products; and
 - . Conducts total diet surveys in selected U.S. cities.

USDA Structure

Instead of creating a new organization to implement the Pesticide Data Program (which would duplicate existing expertise), USDA charged four of its agencies with identifying their respective expertise and needs, and then melding them into a comprehensive program. The four USDA agencies are the Agricultural Marketing Service (AMS), the National Agricultural Statistics Service (NASS), the Economic Research Service (ERS), and the Human Nutrition Information Service (HNIS). AMS was selected as the lead agency in coordinating and implementing the various facets of the residue program.

The Pesticide Data Program was developed in stages, so that the integrity of data was not compromised. By taking this approach, the four USDA agencies were able to ensure that the system was reliable and communication channels were in place before expanding the program to generate residue data on additional chemicals and crops.

Agency Responsibilities

Specific responsibilities of the four USDA agencies are:

- AMS**
- . Coordinates the activities of all USDA agencies and of cooperating state agencies;
 - . Coordinates pesticide residue sampling and testing procedures; and
 - . Maintains an automated information management system for pesticide residue data.

- NASS** . Develops and provides statistically reliable state-level agricultural chemical usage data on food crops; and
- . Collects economic input data that link chemical usage with economic characteristics.
- ERS** . Analyzes NASS and AMS data to determine the impact various regulations and production practices might have on U.S. agricultural production, the nation's food supply, and consumers; and
- . Assesses economic implications of alternative pest control policies and practices on producers, marketers, and consumers.
- HNIS** . Conducts nationwide surveys of food used by households and food intake by individuals. This includes collection of data on multiple days of food intake and food intake per eating occasion which makes it possible to estimate both acute and chronic exposures to pesticide residues; and
- . Is developing a Food Grouping System to translate data on foods as consumed into forms that can be linked with pesticide residue data. This system will provide intake data on food and commodities for EPA and other organizations to determine potential residue exposures for the total population and population subgroups.

State Cooperation

AMS has developed cooperative agreements with six participating states -- California, Florida, Michigan, New York, Texas, and Washington -- to collect and analyze fresh produce for pesticide residues. These states were selected because of their history of interest in pesticide residue data, availability of laboratory facilities, staff, technical expertise, regional diversity, and the fact that their produce production is substantial. The combined population of these states represents approximately 40 percent of the Nation.

Scope

By the end of 1991, AMS designated 11 pesticides of interest to EPA for laboratory analysis on each commodity sample being tested for pesticide residues. However, the analytical procedure detected 34 different residues -- and all such residues were reported. Capability exists to detect additional compounds, as evidenced by new pesticide findings each month.

AMS selected three commodities for initial sampling -- grapes, lettuce, and potatoes. Oranges, grapefruit, bananas, and apples were added by the end of FY 1991. Celery, green beans, and peaches were added early in 1992.

Complexity

All detected pesticide residues are verified and meet very sensitive detection requirements. The PDP is designed to detect and report low level concentrations of pesticides in commodities. The program also provides data on the edible portion of a product sampled at the distribution level near the consumer food consumption level. Residue data, coupled with toxicology and food consumption data, can then be evaluated as part of the EPA pesticide risk assessment process. Maintaining a quality residue data base requires standard sampling and uniform state laboratory procedures, and an effective quality assurance program. To accomplish this, state-of-the art, standardized instrumentation was installed in cooperating state laboratories.

Current Status

As of March 1992, 10 fresh fruit and vegetables were being sampled and tested. Chemical analyses were being performed on two additional pesticides, bringing the number of pesticides of interest to EPA to 13. Analyses were also being performed for additional pesticide compounds.

Results from AMS's 1991 pesticide residue program will be published in March 1992. A cooperative agreement is being developed with USDA's Animal & Plant Health Inspection Service to use the National Residue Monitoring and Analysis Laboratory at Gulfport, Miss., for speciality analysis (e.g. benomyl and herbicides). Other States are under consideration for participation in PDP. In addition, NASS will release the results of its usage survey on fruit and nuts in June 1992.

Future Actions

Contingent on future funding, PDP will expand to further meet the residue data needs of EPA. The order of priority for expansion will be to: (1) Include more pesticide residue analyses (especially those compounds requiring individual analytical methods as contrasted with methods capable of detecting multiple residues); (2) increase the number of fresh commodities sampled; (3) provide for sampling operations in additional States; (4) develop improved sampling plans and an automated information management system; and, (5) expand to meet the needs of State government agencies as well as other users.

Summary

The Pesticide Data Program is designed to meet the data quality and random sampling criteria required for risk assessment studies. USDA is confident that this program is needed for making decisions on food safety issues and addressing public perceptions concerning the safety of the Nation's food supply.

Pesticide Data Program

January - June, 1992 Report



Agricultural Marketing Service

U.S. Department of Agriculture



United States
Department of
Agriculture

Agricultural
Marketing
Service

P O. Box 96456
Washington, DC
20090-6456

July 1993

To the Reader:

In May 1991, the Agricultural Marketing Service of the United States Department of Agriculture implemented the Pesticide Data Program (PDP) to collect objective, comprehensive data on pesticide residues for fresh fruits and vegetables. This program was submitted to Congress as part of the President's 1991 budget to address the increased interest in food safety by producers and consumers.

This program was designed to provide government agencies with an improved data base to respond more effectively to food safety issues. The primary recipient of the program's data will be the Environmental Protection Agency, which will use this information to support its risk assessment process.

The enclosed report provides residue data for the first six months of calendar year 1992. PDP has been funded by Congress and is operated through Cooperative Agreements with participating States, which have the responsibility for sample collection and analysis. Through the end of 1992, there were six participating States as follows: California, Florida, Michigan, New York, Texas, and Washington.

The program was expanded during the last six months of 1992 to include additional commodities and pesticide classes. This information will be reflected in the full PDP Calendar Year 1992 Report, which will be published in the fall of 1993. Program operations were expanded once again in January of 1993 to include three new participating States. The addition of these States--Colorado, North Carolina, and Ohio--increased the segment of the Nation's population represented by PDP sampling to approximately 50 percent, and also provided for a greater degree of regional diversity.

We welcome comments regarding this report. Comments should be addressed to:

Dr. Craig A. Reed, Director
Science Division
Agricultural Marketing Service
U.S. Department of Agriculture
P.O. Box 96456 (Rm. 3507S)
Washington, DC 20090-6456



The Agricultural Marketing Service
is an agency of the
United States Department of Agriculture

CONTENTS***List of Figures, Tables, and Appendices******Executive Summary*****1.0 INTRODUCTION**

- 1.1 1992 Program Operations, January-June
- 1.2 1992 Program Operations, July-December Preview
- 1.3 1993 Preview

2.0 SAMPLING OVERVIEW

- 2.1 Sampling Procedures
- 2.2 Statistics on Samples Collected

3.0 LABORATORY OVERVIEW

- 3.1 Quality Assurance Program
- 3.2 Sample Preparation
- 3.3 Sample Analysis

4.0 SAMPLE RESULTS

- 4.1 Multiple Residues Detected
- 4.2 Non-Detected Residues
- 4.3 Tolerance Violations

LIST OF FIGURES, TABLES, AND APPENDICES**FIGURES/TABLES**

Figure A.	Overview of PDP Management and Operations
Figure 1.0	Pesticides in PDP
Figure 1.1	Areas of Distribution of Participating States
Figure 2.0	Commodity Distribution Percentages
Figure 2.1	Origin of Domestic Samples
Table 1.	Distribution of Pesticide Residue Concentrations by Commodity
Table 2.	Quantifiable Concentration Detected vs. Established Tolerances

APPENDICES

Appendix 1	State Sampling Collection Dates
Appendix 2	Sampling Regions by State
Appendix 3	Sample Profile by Origin
Appendix 4	Sampling Period and Distribution by Commodity
Appendix 5	EPA Targeted Pesticides in PDP - Tolerances
Appendix 6	Other Pesticides in PDP - Tolerances
Appendix 7	EPA Targeted Pesticides in PDP - LODs and LOQs
Appendix 8	Other Pesticides in PDP - LODs and LOQs
Appendix 9	Distribution of Residues Detected by Commodity
Appendix 10	Distribution of Residues Detected by Pesticide
Appendix 11	Multiple Pesticide Residues Detected
Appendix 12	Tolerance Violations Reported to FDA
Appendix 13	Chemical Action of Pesticides Detected by PDP

EXECUTIVE SUMMARY

Background

In May, 1991, the U.S. Department of Agriculture implemented the Pesticide Data Program (PDP) to collect objective, comprehensive data on pesticide residues in fresh fruits and vegetables. By having access to pesticide residues which are measured as close to the consumer level as possible, the Environmental Protection Agency can more accurately determine exposure, and thus better estimate dietary risk to the consumer. PDP is a multi-agency program with planning, policy, and procedural efforts coordinated among the U.S. Department of Agriculture (USDA), the Environmental Protection Agency (EPA), and the Food and Drug Administration (FDA). All data produced by PDP will be available for use by EPA to conduct dietary risk assessments, address pesticide reregistration issues, and complete the special review of specific pesticides. Figure A gives an overview of program management and operations.

To expedite program implementation, AMS established Cooperative Agreements with agencies in six States (California, Florida, Michigan, New York, Texas, and Washington) to collect and analyze PDP samples. These States were selected because they represent diverse geographic areas of the country, approximately 40 percent of the Nation's population, and a large percentage of the fresh fruits and vegetables grown in the United States. Commodities chosen for inclusion in the program were among those most prevalently consumed by the American public, and pesticides targeted for data collection were selected by EPA in consultation with USDA. Participating States were assigned a specific number of samples to collect per month based on each State's population. Samples were collected at sites such as terminal markets and large distribution centers, which allows for sampling as close to the consumer level as possible. Sampling at these locations also provides grower and packer information, post-harvest pesticide use, and takes into account pesticide degradation that has occurred during transit and storage.

1992 Program Operations, January-June

The January-June 1992 Report presents the data for the first six months of 1992. The number of commodities included in the program remained at 7 in January, but was increased in February to include celery, green beans, and peaches, for a total of 10 commodities. The participating States remained at six, with a total of eight testing facilities. A USDA regional laboratory, needed to perform special analysis, became PDP's ninth testing facility in May.

Each State provided AMS with a quarterly sampling plan following PDP sampling guidelines, which required that sampling dates and sites be selected at random. Uniformity of sampling technique and strict adherence to the guidelines were emphasized. Participating laboratories were required to meet rigorous quality assurance/quality control (QA/QC) criteria. To facilitate this goal, PDP provided similar instrumentation for each laboratory and provided training on instrument use that was tailored to program needs.

During the first six months of 1992, some 2,859 samples were collected and analyzed. Individual allocation of samples by State was as follows: California (769), Florida (435), Michigan (386), New York (507), Texas (487), and Washington (275). These produce samples originated from six participating States, 25 other States, and 13 foreign countries. Of the 2,859 samples, 1,664 (58%) contained detectable levels of 1 or more pesticides.

The data collection requirements and advanced analytical technology utilized by PDP have resulted in a significant number of residue detections in some commodities. For example, in apples, celery, grapes, and peaches, approximately 80 percent of the samples tested contained detectable residues, and in some cases more than one residue was detected in an individual sample. However, as many as 47.2 percent of all residues detected were below 0.10 parts per million, with 7.6 percent of the detections below 10 parts per billion.

In general, the levels of pesticide residues detected were substantially below tolerances. Violative residues were detected in 19 of the samples, 6 of which were in imported commodities. Of the 19 violations found, 5 exceeded the tolerance level and the other 14 had residues where no tolerance is established. Although PDP does not have enforcement authority, AMS and the States do notify FDA when violations are found. This data may assist FDA by pinpointing areas where closer surveillance may be required.

1992 Program Operations, July-December Preview

As of July 1, 1992, samples collected in all six participating States were being analyzed for 2,4-D and bromoxynil. On July 20-23, AMS hosted the fifth PDP Federal-State Meeting in conjunction with the Florida Pesticide Residue Workshop. The Sampling and Laboratory Standard Operating Procedures (SOPs) were discussed at the meeting, both of which were completed in December.

In August, AMS established Cooperative Agreements with Colorado, North Carolina, and Ohio for sample collection only. These three new States and AMS agreed that samples collected would be analyzed by one or more of the other participating laboratories. The addition of these States increased the segment of the Nation's population represented by PDP sampling to approximately 50 percent and also provided for a greater degree of regional diversity.

Broccoli and carrots were added to the program October 1, for a total of 12 commodities. On October 20-21, AMS hosted the 6th PDP Federal-State Meeting. Among topics discussed at the meeting were modifications to the PDP sampling protocol to alter the probability of site selection.

The PDP Calendar Year 1992 Report, summarizing pesticide residue data for all of 1992, will be published by the fall of 1993. This annual report will also provide more detailed information on distribution ranges of residue levels for selected pesticide/commodity pairs.

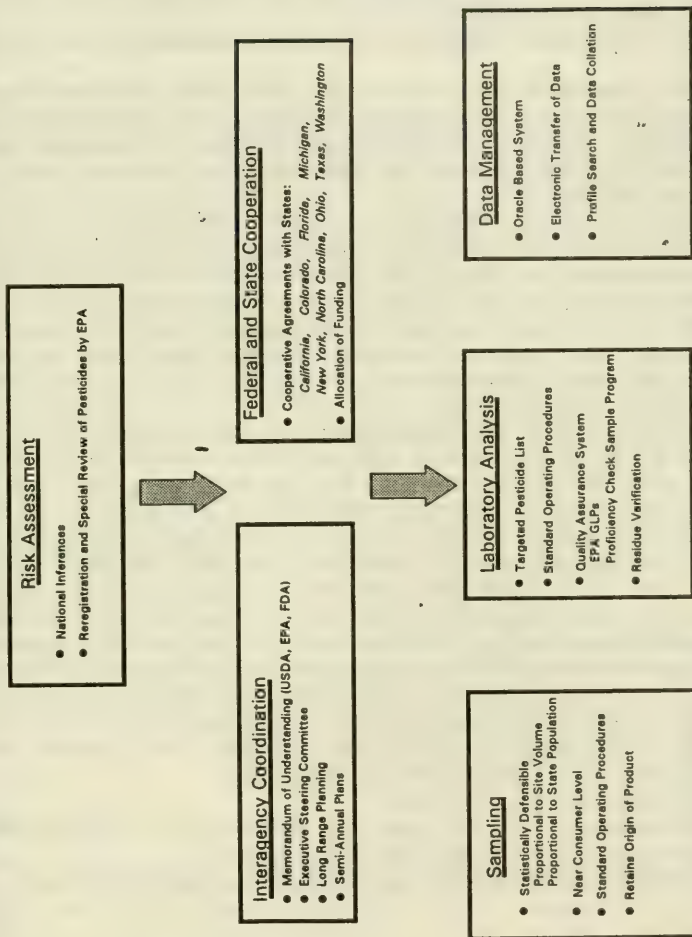
1993 Preview

In January 1993, PDP implemented a statistically defensible sampling plan whereby the probability of site selection is based on the amount of produce distributed by the site. This plan was developed with the statistical support of the USDA National Agricultural Statistics Service (NASS), which will provide long-term maintenance and support for the sampling system. Information obtained through PDP sampling provides data which can be used to make national inferences based on the States sampled. Sample collection and analysis for the three new States also began in January, as well as testing for at least five selected N-methyl carbamates.

Formetanate analysis for apples and peaches will begin in July 1993, whereas analysis for grapefruit and oranges will begin later in the year.

Testing procedures will be evaluated for additional pesticides such as avermectin, ethephon, oxadixyl, propargite, thiodicarb, and thiophanate methyl.

FIGURE A OVERVIEW OF PDP MANAGEMENT AND OPERATIONS



Mr. ROMINGER. They haven't been released yet.

Mr. STENHOLM. Is this the first data that has ever been released? Starting in 1989?

Mr. ROMINGER. No. 1991 was released previously, and this is the 1992 that is coming now.

Mr. STENHOLM. Did the 1991 data indicate that we had a problem?

Mr. ROMINGER. As I recall, the 1991 data indicated that we did detect residues on somewhere in the 20 percent range of products that were tested; but almost all of those, 98 percent of it, was below the tolerance level. So there are residues out there, but they are all very minimal.

And I think the 1992 data will show that, as our science has increased, or techniques have increased, we are able to find more of those residues out there; but they are still at very low levels.

Mr. STENHOLM. Mr. Kimm, do you concur with that?

Mr. KIMM. Yes; it is hard to generalize about residue data. It is a complicated process working through the States to collect the data. In some instances we have already used this data to help us in our risk assessments.

Typical in our risk assessments, we try to look at the best data that we have that would represent the residue levels that people are actually exposed to. And for the most part, the detected residues compared to tolerances and those kinds of things.

Mr. STENHOLM. We have a vote in progress, so this is your lucky day. We are not going to hold you here, and we won't ask you any of these other terrifically important questions that I intended to ask you here today. We will let you go, and we look forward to hopefully you beating the September 1 deadline with some concrete suggestions for this committee. We intend to move forward with you, as you suggested in your testimony, on a cooperative venture with the administration and this committee.

We look forward to doing that, and we look forward to working with you. Thank you for being here today.

This hearing is adjourned.

[Whereupon, at 2:05 p.m., the subcommittee was adjourned, to reconvene, subject to the call of the Chair.]

[Material submitted for inclusion in the record follows:]

STATEMENT OF

MAUREEN KUWANO HINKLE
DIRECTOR, AGRICULTURAL PROGRAM

NATIONAL AUDUBON SOCIETY

Mr. Chairman and members of the Subcommittee, I am Maureen Kuwano Hinkle, and I have directed Audubon's agricultural policy program since 1981. Before that I worked for the Environmental Defense Fund watchdogging implementation of the FIFRA from its first overhaul in 1972. On behalf of the National Audubon Society I am pleased to be asked to present this statement on current pesticide registration, reregistration processes, minor-use pesticides and alternatives to conventional chemical pesticides.

The National Audubon Society has been concerned with pesticide regulation since the 1950's when some of our members in the South became concerned over the application of Heptachlor for imported fire ant control. It was our members who, in 1972, discovered dozens of golden eagle carcasses which had been thrown into a Wyoming canyon after they had fed on coyotes killed by the predicide, thalium. Audubon was also active in the legislative battle that gave the newly established EPA authorities to regulate pesticides in 1972.

In the past twenty-one years, FIFRA has been changed only twice: in 1978 to open up trade secrets, and in 1988 to accelerate reregistration. Audubon was active on those efforts, as well as in the many failed efforts to amend FIFRA.

Unfortunately, the gridlock that plagues FIFRA has resulted in poor administration of the law and poor regulation of pesticides. This paralysis has contributed to a lack of public confidence in the regulation of pesticides and in the companies who manufacture pesticides. Regulation has been notoriously inefficient. Morale at EPA, so high in the 1970s, has eroded with time. We can no longer afford to squander the public's money or patience. Today we are at a threshold, as EPA prepares to become a full-fledged member of the Cabinet.

Reregistration

From the outset, the principal preoccupation of EPA has been with reregistration. This is understandable as organic pesticide development was a direct consequence of the all-out investment in organic chemistry research by government and industry for the entire half-century since World War II. Agricultural research could not have justified this investment by itself, but the resulting knowledge base fosters chemical controls which led to most of the chemicals we know today.

The existing knowledge base on old chemicals and the registration process itself is geared to reregistration of existing chemicals. It is cheaper by far to defend reregistration of old chemicals than initiate studies for new chemicals. Accordingly, most of the work being done on pesticides is defensive work on old chemicals. The requirements are also less onerous for reregistrations, whereas, requirements for new compounds are more stringent. At the same time, new chemistries are more complex and expensive to identify and develop. In addition it is cheaper to run chemical trials, than to identify and pursue application strategies for biologically-based control agents.

Need for alternatives

Why should we be concerned if companies are spending their own money to defend old registrations? Their regulation is, of course, necessary, but even if all reregistrations were cleared, growers need more tools than they now have.

Resistance. When Rachel Carson warned in 1962 that repeated pesticide use would create a crisis in which "only the strong and fit remain to defy our efforts to control them," 137 insects were resistant to pesticides. Today, resistance has been documented in 504 species of insects and mites, 273 weeds, 150 fungi and other plant pathogens and five kinds of rats. Most alarming, there are at least 17 insects that are resistant to all major classes of pesticides. As North Carolina State University professor, Fred Gould, puts it, "Since the DDT case [of resistance] the insects have, as a group, never met a chemical they couldn't take to the mat." Another way to put it, resistance is removing chemical pesticides faster than EPA can regulate them. Growers need alternative pest controls.

Exotic pests. An equally important need for alternatives stems from the stark realization that the introduction and spread of foreign pests into the U.S. is increasing. A major OTA study requested by the Energy and Commerce and the Merchant Marine Committees is expected to be released soon. That study will document how human impact on the earth has provided many, new sites that are ripe for invasion of exotic species -- plants, animals and their diseases. The rapidity with which we can travel around the world today facilitates unintentional introductions of exotic pests and diseases. The result is that we have more established pests than we can control with current means. Growers and other land managers need a range of control tactics.

Other problems. Apart from these two problems of resistance to chemicals and advent of new pests, there are equally serious problems posed by existing chemicals to human health and the environment, such as diminished wildlife, ground and surface water contamination, and even ozone depletion. Growers and land managers need control agents that are less intrusive of the ecosystem in which they are released.

The knowledge base in ecological sciences is very small, yet it is necessary if growers are to have the tools they need to control super pests and new pests. The value of such basic information to the progress of applied research is recognized in agriculture. The priority given to genome mapping programs in support of traditional breeding programs is the latest example. There is no comparable effort for microbial ecology.

We need to pave the way for alternatives to conventional chemical pesticides, and this must include innovative strategies and tactics. Pests not only adapt to agricultural pressures and pesticides, they also interact with other environmental factors. USDA has tried to assess benefits based on empirical field research concerning pest damage to crop yields and quality. USDA wants to assess benefits based on empirical field research concerning pest damage to crop yields and quality, but they do not have satisfactory baseline data. **USDA needs to give high priority to biological**

controls which require a considerable knowledge base, but have never received the emphasis or the funding it should have.

Minor uses. When the market is small, there is no more incentive for chemical companies to seek registration of minor uses than there is incentive to register non-conventional pest control agents. A limited market for chemical or non-chemical products, whether new or old registrations, has limited economic return. Similarly, registrants are unwilling to invest money in narrow-spectrum, target-specific compounds. Yet most of these are the new generation of chemicals and non-chemicals that are not harmful to human health, will not be intrusive in the environment, and will provide more enduring control of the target pest.

This is the crux of the problem -- a problem most immediately experienced by minor crop growers: low/no return on investment means no product commercialization. Although some technologies are currently available right now, the overall picture is very bleak. Unless there is a significant increase in funding for research and development of alternatives, and incentives provided for those who wish to pursue their commercialization, there will never be the variety and number of control agents needed by growers and other land managers.

In the last session of Congress, Rep. Charlie Rose (D-NC) sponsored provisions for a range of incentives for new generation pesticides. That was the first time that either chamber addressed itself to examining ways to encourage the development of, and to reduce the obstacles to, registration of non-conventional pest control agents. Without action from Congress, the research, development and commercialization of alternative control agents will continue to languish. Audubon urges Congress to build upon the incentives contained in the New Generation Section of HR 3742, the Pesticide Safety Act of 1992.

EPA is so preoccupied with reregistration, that new biologically based agents are not given much attention, let alone any priority. Products that are essentially non-toxic, unlikely to be used extensively, and are very selective, must be given a regulatory fast track if they are ever to be available to growers. Therefore, EPA should be required to organize and consolidate existing resources to form teams from all divisions. These teams should function as a critical mass to accelerate the evaluation process for all non-conventional pesticides.

At the same time, USDA should launch a policy of instructing extension officials in strategies and tactics oriented toward reduced pesticide use and identification of natural controls existing in the areas where they work.

In regard to minor uses, the "free ride" that the Minor Crop Alliance is requesting will bring little long-term benefit to growers, and would only add to the inefficiencies that now burden the dwindling resources at EPA. Minor Use legislation must be tied to alternative control agents for minor crops.

Redefine Benefits

Rarely has all available cropland been in production.* Each year, farmers must set aside a certain proportion of their land to qualify for program benefits. Pesticide use has often led farmers to crop more intensively on the land allotted by USDA.

If Realistic Yield Goals (RYGs) were to replace annual set asides as a production control device, more land in production could be cropped less intensively. RYGs are based on a limit to the realized yield benefits of increased applications of nitrogen fertilizers and chemical pesticides. In many areas these limits have already been established and guide the use of agricultural chemicals, but they have not been factored into a benefits analysis. After such limits have been empirically established by USDA, EPA should be required to define benefits according to such established RYGs, instead of increased yields per acre per year *ad infinitum*. By redefining benefits, EPA would help growers be more sustainable.

Audubon urges Congress to require USDA and EPA to work together to empirically establish Realistic Yield Goals for all commodity crops, and to define benefits accordingly.

Pesticide Use Reporting

Section 1491 of the Food, Agriculture, Conservation and Trade Act of 1990 (7 USC 1421) provides for the Secretary of Agriculture in consultation with the Administrator of EPA to require certified applicators of restricted use pesticides to maintain records comparable to records maintained by commercial applicators of pesticides in each State. The state also directs USDA and EPA to publish annual comprehensive reports on pesticide usage. Although a good precedent in enabling USDA and EPA to require reports on actual pesticide use of at least restricted-use pesticides, there is widespread recognition that only a partial picture will ever be possible, given the inadequacies of the requirements.

Actual pesticide use data is undoubtedly the best answer to a host of problems that have proven intractable over the past several decades. In the absence of actual pesticide use surveys, EPA applies a theoretical maximum residue concentration when calculating the possible risk posed by a proposed tolerance level. With actual pesticide use data, EPA could use a scalpel for regulatory purposes instead of the regulatory sledgehammer. Rather than extrapolation, EPA could know what use patterns prevail on which crops, and could then proceed to require use reductions where they are unnecessarily high or where they are sufficiently high to raise safety concerns.

* Set-aside programs in operation for over 50 years, removed an average of 15 million acres per year from 1935-1960. From 1960 to 1985 an average of 34 million acres per year were removed in set-asides. Although set asides were very high in some years, between 1948 and 1956 and between 1979 and 1981 no land was set aside.

Of equal importance, farmers need good records for their own business use. Growers keep records of their costs, profit, loss for tax purposes, and they must be able to assure creditors and insurance companies that they are "free of hazardous wastes or toxic build-up."

USDA needs actual pesticide use data for benefits analysis, and in their search for good economic data on pest damage to crop yields and quality.

In reality, EPA, USDA and FDA need actual pesticide use data to improve and make possible efficient management and regulation of pesticides. Without such data, none of the involved agencies will be able to resolve public safety issues with assurance, and farmers will continue to shoulder the burden of a suspicious public.

Audubon recommends that three changes be made to Section 8(b) of FIFRA and Section 1491 of FACTA. First, private applicators should be required to keep records of general use pesticides as well as restricted use pesticides.* Second, those persons applying pesticides to more than a certain number of acres of agricultural land in a calendar year, should also be required to keep records. Third, additional information should be required in order to be useful.

Resistance Management

The Food Security Act of 1985 authorized USDA to develop a strategy for the establishment of a national pesticide resistance monitoring program, involving Federal, State, and local agencies, as well as the private sector (Sec. 1437(a)(3) of PL 99-198). A 1986 report set forth components of the national program, and USDA is mandated to compile a data base to track pest resistance data *inter alia* and provide such data to EPA on an annual basis under Section 28 of FIFRA. The Food, Agriculture, Conservation and Trade Act of 1990 mandated USDA to establish a data base on the extent of pest or disease resistance determined by a monitoring program. (Section 1651(a)(2) and (d) of PL 101-624).

On January 22-23, 1992, USDA held a conference on resistance management strategies. Among the suggested approaches were economic incentives for farmers to restrict their indiscriminate use of *Bacillus thuringiensis* (Bt), requirement for participation in an IPM program to qualify for use of transgenic plants, and required registrants to monitor and report development of resistance

* Currently there are 2,173,000 farms and some 2,753,00 farm operators (owners, managers or tenants) half of whom would be required to keep records. This is an estimate based on 1986 information that pesticides were purchased by approximately 57% of all farms.

There are 250,268 commercial applicators currently reporting pesticide usage as a condition of certification. Another 1,019,978 private applicators keep records of restricted use pesticides only, which constitute about 10% of all pesticides applied. The other 1.3 million who are not certified either hire private or commercial applicators or do not apply pesticides.

USDA and EPA should address resistance management strategies to prevent and delay resistance to existing chemicals and to new ones, such as plants that manufacture pest control agents.

Conclusion

National Audubon believes that the opportunity to reform FIFRA is stronger than it has ever been. Other environmental groups will comment more extensively on the need for speedier cancellation and suspension procedures, enforcement, fees and penalties, special protection for children, and circle of poison. These are all issues which Audubon has covered in previous statements before the subcommittee. Audubon has focused this statement on the following priorities:

There is a critical need to research, develop, and bring to market alternatives to conventional chemical pesticides that conserve natural controls existing in the environment. Congress needs to eliminate obstacles to the development and marketing of such control agents, and to establish a range of incentives to encourage their development.

Benefits should be redefined in such a way that increased yields per acre per year are no longer the norm. In its place should be Realistic Yield Goals (RYGs) that will make sustainability a reality on every acre of cropland.

Recordkeeping of actual pesticide use is essential for EPA, USDA and FDA to get a handle on their respective and collective responsibilities regarding use patterns, use reductions, and realistic tolerance setting.

Resistance management should be employed to ensure constructive use of pesticides

Any minor use remedy needs to be tied to incentives for alternative control agents that are ultimately essential for minor use crops.

The National Audubon Society believes enactment of these recommendations would constitute a breakthrough for EPA that would benefit everyone -- growers, government agencies, potential registrants, the environment, and the public at large. These proposals would bring the relevant agencies together to work out problems of mutual concern in new ways, and would add efficiency, purpose and clarity to the regulatory process. Working out the details would be welcomed with enthusiasm. We would like our energies to be dedicated toward raising FIFRA out of the doldrums.

Thank you for this opportunity to set forth these ideas.

TESTIMONY OF ERIK D. OLSON
SENIOR ATTORNEY
NATURAL RESOURCES DEFENSE COUNCIL

I. INTRODUCTION AND OVERVIEW.

Chairman Stenholm and distinguished members of this Subcommittee, I am Erik D. Olson, Senior Attorney with the Natural Resources Defense Council (NRDC), a national non-profit public interest organization dedicated to protecting public health and the environment, with over 170,000 members nationwide. We appreciate this opportunity to testify today regarding pesticide reform and the updating of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

Simply put, FIFRA has been a failure. It has failed to provide farmers an orderly, predictable, and timely review of pesticides and to encourage the development of alternatives to problem pesticides. It has not protected farmworkers from poisoning. It has been unable to assure public confidence that the government has prohibited contamination of foods and drinking water with pesticides. It has not prevented environmental problems ranging from pesticide contamination of lakes, rivers and streams, to wildlife poisonings and reproductive failures, to fish contamination with pesticide residues.

Unfortunately, the federal government--and USDA and EPA in particular--has failed to provide farmers with the tools they need to predict what will be available next year, and to make the transition to reduced reliance on toxic and environmentally dangerous pest control methods.

Thus, FIFRA and much of our agricultural policy have been ineffective from the farmer's and the public's perspective. It

has failed, first and foremost, the farmers in being unable to assure an orderly process is provided that will ensure that dangerous chemicals are removed from the market and alternatives to those chemicals are developed and demonstrated in a meaningful way to farmers so that they may adopt those alternatives. Even where the need for some action is clear, there have been decades of delay, such as in the case of parathion, which has been known to have poisoned hundreds of workers.

FIFRA also has failed to protect the nation's lakes, streams, rivers, and groundwater from pesticide contamination; for example, the U.S. Geological Survey recently released data documenting that in the Mississippi River basin, 27 percent of the water samples taken exceeded the EPA drinking water standard for a single herbicide, atrazine.¹ Earlier studies by USGS had found that 98 to 100 percent of the 150 streams tested in 1990 contained herbicides.² Many other pesticides also were found to contaminate this major source of the nation's heartland's drinking water,³ yet virtually none of the public water systems in the United States is currently equipped to remove pesticides from their source water. EPA also has found that about one out of ten public water supply wells contains pesticides; EPA infers

¹USGS, Distribution of Selected Herbicides and Nitrate in the Mississippi River and its Major Tributaries, April Through June, 1991, USGS Water Resources Investigations Report 91-4163 (1991).

²Ibid; USGS Press Release "Spring Sampling Finds Herbicides Throughout the Mississippi River and Tributaries," November 20, 1991.

³Ibid.

from these data that "nearly 10,000 community drinking water wells, and about 446,000 domestic water wells" contain pesticides. Yet the Agency has been paralyzed by the lack of statutory authority and mandate, as well as by a lack of will, to aggressively intervene to protect the nation's water resources. Generally, EPA has tried to punt these issues to state or local authorities, with no assurance that these largely "voluntary" programs will help.

Moreover, FIFRA has failed to redress the need for assuring a safe food supply. Cancer and other risks of pesticide residues on food have been largely unaddressed for decades.

As we are in the process of developing detailed legislative proposals for pesticide reform, we will only briefly discuss pending bills such as H.R. 1627, the so-called Bliley-Lehman "Food Quality and Safety Act of 1993," which we vigorously oppose as an effort to substantially undercut even the weak current protections of the food supply from pesticide contamination.

Improvements to Pesticide Regulatory Process.

There is an urgent need to reform certain aspects of the antiquated and woefully inefficient FIFRA provisions for cancellation and suspension of dangerous pesticides. In addition, the enforcement, registration, and certain other provisions of the law also need to be updated. Moreover, while we are not unhappy with the Delaney Clause and the recent Court decision that will force EPA to finally implement that law, we are interested in broadening protection of food safety through

more comprehensive food safety legislation, for which Kennedy-Waxman should serve as a vehicle.

We also urge this Committee to work with the Clinton Administration to adopt a strong FIFRA reform measure, perhaps building upon key portions of Charlie Rose's FIFRA reforms as introduced last Congress (H.R. 3742), that will remedy the problems with the Act as soon as possible. As former EPA Administrator Reilly stated, the current pesticide cancellation

process is very complicated, duplicative, and inefficient. This country cancels trading in bad stock faster than it gets rid of a bad pesticide. ... [We must] address this issue by removing one of the very duplicative parts of the process, the adjudicatory hearing that occurs after a decision has been reached by the EPA administrator on the basis of extensive scientific analysis to cancel a chemical.... Where we now have a four to eight year process from start to finish for cancellation, we ... [urge Congress to adopt reform legislation] to reduce the period to something in the range of two to three years. We have the authority to suspend a chemical under certain circumstances. But that power has only been exercised three times in EPA history. The standard for exercising it is very rigorous. The courts have in fact found that we proposed to exercise it inappropriately in the past and have prevented us from using this authority.

I got my baptism by fire on these questions ... and really found it astonishing that the statute essentially put the EPA Administrator in the position of defending a decision that concluded, first of all, that the chemical pesticide posed an unacceptable risk and was therefore a candidate for cancellation, but then, nevertheless, left us with the reality that that pesticide was going to be around for several years to come.

That really, I think, is an untenable situation. It's one that has long needed addressing. I think it's one of the strongest elements in this set of proposals [made by the Administration to reform FIFRA], that we remove the adjudicatory hearing, the de novo review that has added so many years to that process, and I would expect that anybody who looks at that will recognize that this is going to make

for a much stronger and more protective implementation of that law.⁴

Chairman Rose's bill of last year as introduced would have streamlined EPA's cancellation and suspension process, in an effort to reduce the procedural problems identified by Administrator Reilly. While a few changes to the cancellation and suspension provisions in Title I of the Rose bill as introduced are needed to assure that it will achieve its intended effect, in general we supported Mr. Rose's efforts to reform FIFRA's cumbersome cancellation and suspension procedures, and opposed weakening amendments that were attached to the bill in markup.

We also were pleased that the Rose bill provided for mandatory review of pesticide tolerances (although we believe that more frequent review than required by the bill is necessary). In addition, the bill included some needed improvements to FIFRA's enforcement and certification and training requirements, although we believe these provisions needed to go further to assure pesticides are used safely. These reforms, and certain other measures to update FIFRA, are needed to make the pesticide regulatory scheme work for America. We look forward to assisting Congress, the Administration, and other interested parties in reforming this Act.

⁴William K. Reilly, EPA Administrator, at Press Conference on the Administration's Food Proposal, October 26, 1989 (transcript by Federal News Service, Federal Information Systems Corporation, dated October 27, 1989).

B. Problems With Proposed Food Safety Legislation.

Despite the improvements to FIFRA proposed in some sections of the Rose bill, we opposed the legislation because it included other provisions that, while we are sure they were not intended to do so, would weaken current law and would undercut the protection of public health and the environment. We also oppose H.R. 1627, the Bliley-Lehman bill, which we believe is far too weak to assure food safety.

1. Preemption of Local Authority to Protect Citizens

First, the Rose bill and the Bliley-Lehman bill would preempt, to varying degrees, local governments from regulating pesticides, a right that they have enjoyed since pesticides were first invented, and that the Supreme Court now has confirmed has always existed. While the local preemption provision in last Congress' Rose bill theoretically allowed local regulation if it is first approved by the state under a plan approved by the federal government, the cumbersomeness of this procedure, and the numerous points provided for opponents to put the brakes on local rules, made it unlikely that this theoretical process allowing local rules would ever have been used.

Local governments should be able to continue unimpeded their sparingly-used authority to impose such reasonable measures as requiring signs to be posted after pesticide spraying, to control or prohibit spraying above public drinking water well fields or around unprotected surface water intakes for drinking water

systems, and to prohibit aerial spraying on school yards, for example.

Any unreasonable local rules that theoretically may be proposed or adopted could be rejected after local debate, and if they conflict with or impede implementation of state or federal law, would be preempted under current Supremacy Clause law. Moreover, any local rule that unduly burdens interstate commerce would be prohibited by the Courts under current Commerce Clause doctrine. Thus not only is preemption of local authority unwise, it is unnecessary.

2. The Need for Stronger, not Weaker Food Safety Provisions.

Second, both the Bliley-Lehman bill and the Rose bill's provisions revising the Federal Food, Drug, and Cosmetic Act's (FFDCA) pesticide residue-related provisions, are fundamentally flawed, and would give EPA the discretion and in some areas even the mandate to provide less protection of public health than is provided under current law. Thus, if the choice were between the Bliley-Lehman bill, Title II of the Rose bill, or current law, we believe that current law is clearly preferable. The most important problems with these bills' FFDCA provisions are:

- (a) The Bliley-Lehman bill allows an ill-defined level of "negligible risk" from pesticide residues; the Rose bill would have allowed a "negligible risk" defined as one in a million. Yet the bills as drafted apparently allow each pesticide residue's risks to be calculated on an extremely narrow basis. The Bliley-Lehman bill allows so much leeway

to EPA that virtually any risk could arguably be allowed as "negligible." Thus, under these bills' approach, a pesticide applied to scores of crops could be used on each of those crops at a given risk level, posing total risks many times higher than the "one in a million" risk level for all crops to which the pesticide is applied. The bills also fail to assure full protection of children and sensitive subpopulations.

- (b) The bills provide an escape clause allowing pesticides posing even greater risks to be used if the pesticide has certain "benefits." These escape hatches are quite broad. Even the Rose bill's so-called "bright line" standard of "one in a million" given in the subsection before the benefits escape clause is essentially eradicated by the broad and vague cost-benefit language in the following paragraph.
- (c) The bills also would weaken current law by generally preempting states from adopting tolerances more stringent than any new EPA tolerances for pesticides. States always have had the authority to adopt such tolerances, and despite horror stories conjured up by pesticide industry lobbyists, only in a few well-justified cases have states used this authority. Again, like the local preemption provision, this state tolerance preemption provision is unjustified and unnecessary. Not only have states only sparingly used their longstanding authority to adopt these tolerances exclusively

in the most limited and necessary circumstances, but any ill-conceived state tolerance that theoretically could be adopted could be challenged in state courts as unjustified or in federal courts as an undue burden on interstate commerce under the Commerce Clause. The only exception to the ban on stricter state tolerances would be that EPA could allow a state to adopt such a tolerance if EPA finds it is "warranted by special local circumstances in the state."

3. Minor Use

While we are sympathetic to certain grower concerns with the possible loss of so-called "minor use" pesticides, we are very concerned about the breadth and vagueness of certain language in the minor use legislation introduced to date. For example, the minor use bills would provide lengthy extensions of data submission and other deadlines to allow pesticides to remain on the market, apparently even if the carcinogenicity, ongogenicity, teratogenicity, and reproductive toxicity studies have not been done on the chemical. It is important to note that much of the calculated cancer risks from pesticide residues come from so-called "minor use" crops like fruits and vegetables. Even if these toxicological studies have been done, the bill apparently would allow the pesticide's use at greater than one in a million risk for "essential" uses. This is a substantial problem, as it is not clear what additional risk would be allowed nor what an "essential" use would be.

There is a need to fully fund IR-4 and other programs to assist in collection of data on minor uses, and to identify alternatives to minor use pesticides. There also is a need to create better incentives for growers of minor use crops and for USDA to develop the data needed on alternative pest control methods, rather than creating an incentive to avoid research on these issues, as would be the case under the minor use bills.

II.

PESTICIDES IN FOOD: THE SLOW POISONING OF THE AMERICAN PUBLIC

Several years ago, the Director of EPA's Pesticide Program during the Reagan administration said, "Pesticides dwarf the other environmental risks the Agency deals with. Toxic waste dumps may affect a few thousand people who live around them. But virtually everyone is exposed to pesticides."⁵

More recently, former EPA Administrator Reilly echoed these remarks, stating:

"The [EPA] Science Advisory Board identified pesticides among the top priority concerns, both as they affect applicators and also the consumer of food containing pesticide residues. I propose now that we make food safety a top environmental legislative priority in the new Congress.... President Bush and I both understand

⁵. Shabecoff, P., "Pesticide Control Finally Tops the EPA's List of Most Pressing Problems," New York Times, March 6, 1986.

and share the public's frustration. We know national pesticide laws are arcane and antiquated."⁶

But action has not matched rhetoric. Pesticides continue to be routinely allowed in the nation's food supply with woefully inadequate regulation or even detection. According to the state and federal pesticide monitoring data for the years 1982 to 1985, a total of 110 separate pesticides were detected in 48 percent of the samples tested. Many of these substances have been linked to cancer, nerve damage, genetic mutations and other adverse health effects. However, the full extent of pesticide contamination of the food supply is unknown, primarily because the government's routinely-used residue monitoring techniques do not detect many pesticides applied to food. The Congressional Office of Technology Assessment found that the U.S. Food and Drug Administration's (FDA) primary laboratory method can detect only about half the pesticides registered for use on food. For the rest, we are regulating -- or not regulating -- out of ignorance.

Nearly 70 of approximately 300 pesticides used on food have been classified by EPA as "probable" or "possible" human carcinogens. The cumulative risk to the public health, especially the health of children, from this daily dose of toxic chemicals is unknown. However, disturbing new data indicate an increasing incidence of cancer generally.

⁶. Address by William K. Reilly, Administrator, United States Environmental Protection Agency, to the Commonwealth Club, San Francisco, CA, January 9, 1991.

One out of nine American women will now contract breast cancer during their lifetime, a more than one-third increase in just this decade. Among children fourteen and younger, the incidence of cancer in the United States has increased 21.5 percent from 1950-1986, according to the National Cancer Institute. Other forms of cancer also are on the rise. Even adjusted to account for increases caused by an aging population, there have been sharp increases in: brain cancer (up 22.3 percent), bladder cancer (up 49.2 percent), testicular cancer (up 92 percent), skin cancer (up 263 percent), kidney cancer (up 95 percent) and non-Hodgkins lymphoma (up 130 percent). All new cancer cases combined have risen by 37 percent. New cancer cases, excluding lung cancer, have risen 27 percent. More than one million Americans will learn they have cancer this year; half a million will die from it.⁷

How much of this cancer, and the human suffering it engenders, resulted from pesticides? While EPA has tried to quantify it at six thousand cancers per year, no one really knows. Prudence and common sense dictate that a sound public policy should result in reduction or prevention of exposure to substances known to cause cancer, especially children's exposures.

⁷. National Cancer Institute, 1989, American Cancer Society, 1986. "Cancer Facts and Figures," as cited in Dr. Devra Lee Davis, "Natural Anti-carcinogens: Can Diet Protect Against Cancer?" Healthy & Environment Digest, February 1990.

Regrettably, EPA continues to stress "management" of risk from cancer and other pernicious diseases rather than prevention. As a result of the 1988 amendments to the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) requiring comprehensive testing of pesticides, more and more pesticides found in processed foods are now being determined to cause tumors. They have not been eliminated from our food supply even decades after their cancer-causing potential was revealed. Yet in enacting the Delaney Clause of the Federal Food, Drug and Cosmetic Act Congress expressly and unequivocally prohibited such residues. Rather than comply with the law, the Agency simply chose to try to "amend" it by administrative fiat, both intruding upon the power of Congress and failing to protect the public health as well. The Agency's failure has now been reversed in the courts.⁸ As a result, nationwide injunctive relief may soon be brought to bear on numerous carcinogenic pesticides now being discovered in food.

⁸. Less, et al. v. Reilly, et al., No. 91-70234 (9th Cir. 1992); see also, People of State of California, et al. v. William K. Reilly, et al., No. S-89-0752-RAR-EM (E.D. Cal. May 25, 1989).

III.

POLLUTION PREVENTION:
REDUCING THE USE OF PESTICIDES

The question of chemical residues on the food we eat is a hotly debated issue. The existence of such residues is either played down by the industry as unimportant or is flatly denied. Simultaneously, there is a strong tendency to brand as fanatics or cultists all who are so perverse as to demand that there food be free of insect poisons. In all this cloud of controversy, what are the actual facts? [...]

The system by which the Food and Drug Administration establishes maximum permissible limits of contamination, called "tolerances," has obvious defects. Under the conditions prevailing that provides merely paper security and promotes a completely unjustified impression that safe limits have been established and are being adhered to. As to the safety of allowing sprinkling of poisons on our foods -- a little on this, a little on that -- many people contend, with highly persuasive reasons, that no poison is safe or desirable on food. [...] In effect, to establish tolerances is to authorize contamination of public food supplies with poisonous chemicals in order that the farmer and the processor may enjoy the benefit of cheaper production -- then to penalize the consumer by taxing him to maintain a policing agency to make certain that he shall not get a lethal dose. But to do the policing job properly would cost money beyond any legislator's courage to appropriate, given the present volume and toxicity of agricultural chemicals. So in the end, the luckless consumer pays his taxes but gets his poisons regardless. [...]

This system, however -- deliberately poisoning our food, then policing the result -- is too reminiscent of Lewis Carroll's white knight who thought of "a plan to die one's whiskers green, and always use so large a fan that they could not be seen." The ultimate answer is to use less toxic chemicals so that the public hazard from their misuse is greatly reduced. [...] In addition to making this change to less dangerous agricultural pesticides, we should diligently explore the possibilities of non-chemical methods. A great many other possibilities exist for effective insect control by methods that will leave no residues on foods. Until a large-scale conversion to these methods has been made, we shall have little relief from a situation that, by any common sense standards, is

intolerable. As matters stand now, we are in little better position than the guests of the Borgias.⁹

For three decades since Rachel Carson wrote these stirring words, calls for essential reform of the nation's food safety laws have gone largely unheeded. When governmental agencies or private groups have demonstrated that pesticide regulation is necessary in order to protect public health, a "parade of horrors" has been conjured up by the food and agricultural industries opposing government action. Chemical by chemical, we have been told that pesticides were "essential" to food production and that their elimination, despite clear health hazards, would wreck havoc on segments of American agriculture. Chemical by chemical, after excruciatingly long bureaucratic delays and public debate, these claims were proven false. In the early years, these apocalyptic predictions were made for the chlorinated hydrocarbons (e.g., DDT, aldrin and dieldrin). After years of litigation, these substances were finally removed from the marketplace with no noticeable impact on agricultural yields or production. During the Nixon and Carter Administrations, it was DBCP that stirred the greatest controversy. DBCP is a human carcinogen and potent reproductive toxin. DBCP users and manufacturers claimed that removal of DBCP from the market would have a devastating impact on the production of citrus and other commodities. After a decade of controversy, the pesticide was finally banned, first by California and then by EPA. Citrus

⁹. Rachel Carson, Silent Spring, 1962, pp.182-184.

yields increased. But Americans continue to be exposed to DBCP, which has now contaminated some 2,000 drinking water wells in California alone. A lawsuit brought by the city of Fresno is now pending against DBCP's producers for several hundred million dollars in damages resulting from DBCP pollution of Fresno's drinking water supply. Birth defects and other reproductive harm have already been attributed to DBCP; its long-term cancer impact remains to be seen.

During the Reagan Administration, the spotlight was on ethylene dibromide (EDB), used to replace DBCP and also a potent carcinogen and reproductive toxin. Again Americans were told that EDB was vitally necessary for grain fumigation, as a nematocide used on citrus, and for a variety of other purposes. Again, apocalyptic claims about its proposed removal were made by its producers and by representatives of the food industry. Following years of litigation and a series of scandalous closed-door meetings between high-level EPA officials and the regulated industry, a major public controversy and action by several individual states combined to convince then Administrator William Ruckelshaus to ban the chemical. Interestingly, grain supply did not dwindle and citrus yields did not diminish. Also during the Reagan Administration, heptachlor, a known carcinogen, was found to contaminate much of the milk in the state of Hawaii. Its use had been permitted on pineapples whose leaves were fed to dairy cows. Before this use was finally banned, 90 percent of Oahu's milk had to be destroyed.

During the Bush Administration, the pattern continued. A few years ago, EPA announced its intention to ban the pesticide dinoseb because of highly disturbing test data in laboratory animals demonstrating that it caused deformities of the fetal brain and spine, male sterility and reproductive harm. Representatives of the agricultural industry, particularly from the Pacific Northwest, utilized their political muscle to prevent dinoseb's removal from the market. Again, we were told that the ban of dinoseb would have dramatic adverse economic impacts on the production of caneberries and other crops for which no alternative pest control method was said to be possible. Years later, EPA eventually prevailed in the courts, and dinoseb was removed from the market. The production of caneberries continues unabated.

Perhaps the most notorious case of false claims of "essentiality" is the now well-known case of the growth regulator Alar. Studies linking Alar and its metabolite UDMH to cancer appeared as early as 1973. The EPA proposed to cancel all food uses of Alar in the fall of 1985, but following a series of private meetings with pesticide industry representatives, its use was allowed to continue. In the spring of 1989, a report issued by the Natural Resources Defense Council documented the health risks posed by Alar and UDMH, especially to infants and young children as a result of children's consumption patterns of apple products at levels ten times or more than that of adults. The Environmental Protection Agency stated that the cancer risks

presented by Alar were "unacceptable" and EPA's Administrator "found an inescapable correlation between exposure to UDMH and life-threatening tumors" in laboratory animals. In response, Alar's manufacturer, the Uniroyal Corporation, claimed that Alar's removal from the market would have devastating effects on apple production, yields and quality. Nevertheless, increasing consumer pressure, as well as the threat by Congress itself to ban the substance, finally convinced its manufacturer to "voluntarily" withdraw Alar from the market worldwide. Contrary to industry's claims, since Alar's removal from use, apple yields, price and quality have not diminished.

It is no wonder that public confidence in the food supply has been shaken. It is no wonder that opinion polls consistently show deep-seated public support for reform of the nation's food safety laws. Given this sorry record of crying wolf, claims by industry that purported "benefits" and "essentiality" of known cancer-causing agents must outweigh their health risks should be given short shrift. Rachel Carson was right: "The ultimate answer is to use less toxic chemicals so that the public hazard from their misuse is greatly reduced." In the short term, strict controls should be placed on residues in order to reduce the threat of cancer and other adverse health effects as much as possible. In the long term, given the vagaries of cancer risk assessment and the overall adverse environmental impact of pesticides, including by contaminating drinking water supplies, the workplace, and rural communities, dangerous chemicals should

be phased out of use entirely. Alternative, safer pest control methods should be researched, promoted and used more comprehensively in all sectors of agriculture.

In a report describing EPA's accomplishments, former EPA Administrator William Reilly announced that pollution prevention is the best way to reduce risk. With pesticides, numerous alternative agricultural techniques are already available to reduce the use of these chemicals. Last month, NRDC released Harvest of Hope: The Potential for Alternative Agriculture to Reduce Pesticide Use.¹⁰ This two-year research project revealed that currently available alternative agricultural methods could reduce pesticide applications between 25 and 80 percent in nine U.S. crops.

The promise of alternative pest control remains unfulfilled. Its implementation, which could be greatly enhanced by enactment of the Kennedy-Waxman legislation, with needed improvements. This legislation will not only improve the safety of the food supply. It will also reduce the increasing threat agricultural chemicals pose to the nation's public health, groundwater, and environment as a whole.

¹⁰. Curtis, J., T. Kuhnle and L. Mott, Harvest of Hope: The Potential for Alternative Agriculture to Reduce Pesticide Use, 1991.

C. NRDC'S SUPPORT FOR PESTICIDE LEGISLATION IS CONTINGENT ON CONGRESS' REJECTION OF ALL EFFORTS TO PREEMPT STATE AUTHORITY TO SET STRICTER PESTICIDE TOLERANCES.

Proponents of legislation which would preempt states' authority to set tolerances say that such amendments are needed to prevent a "crazy quilt" of conflicting legal requirements which complicate or interrupt interstate commerce of agricultural produce. Unfortunately, this assertion lacks an empirical foundation. Experience has revealed that states exercise their authority to set more stringent pesticide tolerances cautiously and only in compelling circumstances.

States have acted to set more stringent tolerances only when faced with extreme federal inertia in the face of ample evidence that public health was not adequately protected by federal tolerances. There are approximately 300 pesticides approved for uses on food. Only two pesticides have been the subject of state efforts to tighten federal tolerances: ethylene dibromide (EDB) and daminozide (Alar).

In both instances where states set tolerances more stringent than the federal limits, many years of federal inaction or ineffective efforts preceded state action. In both instances, compelling evidence was available on the basis of which state health authorities concluded that the risks from these pesticides were great, particularly for children. Both times the states tried to motivate the federal government to act and probably would have preferred swift and decisive federal action. The EDB and daminozide incidents did not stem from a surplus of conflicting and overlapping authorities to set tolerances.

Instead, these events demonstrate the confusion and danger which result from the federal government's failure to exercise its authority to revise tolerances when new data reveal high risks. State authority must be retained as a "fail safe" in the event that the federal government fails to diligently and effectively implement the food safety law.

VI.

CONCLUSION

NRDC applauds the Chairman for initiating the review of the pesticide regulatory program. NRDC also believes there is an urgent need for new legislation to streamline pesticide regulation and to ensure that pesticides in food are safe. Legislation of this kind is needed to restore public confidence in our federal programs to protect our food supply. There is no evidence indicating that setting pesticide tolerances at a safe level would result in food scarcities or higher consumer prices for nutritious commodities. The Kennedy-Waxman bill would take an important first step towards better protecting the public, although it does need strengthening. The American public is demanding a vastly safer food supply. We hope to work with this Committee to ensure that the public's demand is heeded.

(Attachment follows:)

APPENDIXPreemption of Local Authority to Regulate Pesticides is Unwise and Unnecessary

NRDC and the environmental community have worked with state and local authorities for many years in efforts to assure that the local police powers generally reserved by the framers of the Constitution 200 years ago to local authorities are not preempted by the federal government under FIFRA. Beginning with the original version of FIFRA adopted in 1947, and continuing with the 1972 FIFRA amendments and subsequent improvements on the Act since then, FIFRA has established what the Supreme Court's recent unanimous decision upholding local authority under FIFRA called a "regulatory partnership between federal, state, and local governments." Wisconsin Public Intervener v. Mortier, 111 S.Ct. 2476, 115 L.Ed.2d 532, 549 (1991) ("Mortier"). As the United States Solicitor General told the Supreme Court on behalf of the U.S. government in supporting the right of local governments to regulate pesticides in the Mortier case, in the pesticide arena, "a local governmental role furthers the overall structure and purpose of the federal statutory program [for pesticides]." U.S. Amicus Brief on Petition for Writ of Certiorari in Mortier, at 16.

Indeed, several federal laws not only encourage such local pesticide restrictions, but in some cases even mandate them. For example, under the Safe Drinking Water Act, local governments are encouraged to protect their local water supplies by adopting rules protecting the wellhead areas and sole source aquifers.

Under the Clean Water Act, EPA encourages local protection measures in conjunction with state measures to protect surface waters from contamination by pesticides and other chemicals, and mandates that local governments develop plans to pretreat waste water and to control surface water runoff that may contaminate local watersheds. This is part of the healthy and longstanding partnership of federal, state, and local governments to protect citizens and the environment. Virtually every major environmental statute mandates a certain level of minimum national protection of public health and the environment, but guarantees state and local government rights to adopt more stringent rules if they find them necessary to protect their citizens or natural resources. Exceptions to this rule have been narrowly crafted to avoid interference with the traditional local police power authorities of state and local governments. For example, FIFRA long has preempted state authorities from "impos[ing] or continu[ing] in effect any requirements for labeling or packaging in addition to or different from those required under this Act." FIFRA section 24(b).

The preemption of local police powers in regulating pesticides proposed in legislation introduced last Congress -- H.R. 3850 and even the somewhat more limited preemption proposed last year in H.R. 3742--would rob local governments of their ability to protect their citizens' health and environment. There remain significant gaps in the FIFRA regulatory scheme that must be filled by local governments, with solutions tailored to local problems, geography, environmental factors, wind and

precipitation patterns, and other local concerns. Thus, as President Bush's EPA Assistant Administrator with responsibility in this area recently stated,

EPA supported the Supreme Court's ruling in Mortier because it affirms the ability of state and local governments to apply pesticide restrictions that are more stringent than federal restrictions under [FIFRA]. We believe that the Court's ruling was based on a correct reading of FIFRA's language and legislative history, and we believe that local governments have an important role to play in the regulation of pesticide use. Local authorities should be able to take into account local or regional factors, such as climate or water supply, in deciding whether to enforce stricter pesticide use rules. For example, the Court's ruling will help to allow communities to protect water supplies from pesticide run-off or protect people, animals, and property from pesticide drift.

Letter from Linda Fisher, EPA Assistant Administrator for Pesticides and Toxic Substances, to Albert H. Meyerhoff, NRDC, dated October 28, 1991.

These local regulations do not--and indeed as a matter of established law under the Constitution's Supremacy Clause they may not--impliedly or expressly conflict with or impede the implementation of any federal law, including FIFRA. Mortier, 115 L.Ed.2d. at 542. Therefore, if compliance with the local law and a federal law is impossible, or if the local law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives" of federal law, the local law cannot stand. Mortier at 543 (internal quotations omitted).

Despite the emotional and dire claims of some, local laws that have been adopted over the past several years in the "laboratory of democracy" at the local level simply have not interfered with or duplicated federal programs or rules. These

iv

local rules are necessitated by the gaps in the federal program, such as the lack of public notice or posting requirements, lack of adequate time or place restrictions on pesticide use in areas such as school yards, and other similar gaps. EPA has, by design, generally left such decisions to local governments, which EPA has said are in the best position to decide whether such local controls are needed.

Moreover, EPA often takes 5 to 10 years to control dangerous pesticides on the market, and numerous reports have documented the Agency's failure to re-register pesticides in a timely fashion or to adequately control lawn use chemicals.¹¹ The agency's failure to adequately control the risks of pesticides contaminating groundwater and punting of this issue to states and local governments is of particular concern.¹² Similarly, a recent USGS study found that over one quarter of the sites sampled in the Mississippi River watershed exceeded the EPA Maximum Contaminant Level for a single herbicide, atrazine.¹³

Thus, many local governments have stepped in to fulfill the need for local governments to adopt time and place restrictions

¹¹See, e.g., GAO, Lawn Care Pesticides: Risks Remain Uncertain While Prohibited Safety Claims Continue (1990); Testimony of Peter Guerrero, GAO, Before Subcomm. on Toxic Substances, Environmental Oversight, Research, and Development, Sen. Comm. on Environment and Public Works (May 15, 1989); GAO, Nonagricultural Pesticides: Risks and Regulation, (1986); EPA, Pesticide Reregistration Progress Report (October, 1991).

¹²See, GAO, Pesticides: EPA Could Do More to Minimize Groundwater Contamination (1991).

¹³USGS, Mississippi Watershed Pesticide Survey, data released in 1992.

to protect local water supplies, to control drift, and to accomplish similar health protection goals. In addition, many school systems and local governments have adopted restrictions on the use of certain pesticides on school property, to prohibit the use of risky roach killers in school cafeterias, to prohibit aerial pesticide applications in areas prone to drift, and to prohibit pesticide applications immediately above wellhead protection areas. Other localities have adopted rules to restrict pesticide applications on their own property or to require that notices be posted to warn parents of young children or sensitive individuals not to enter recently sprayed areas. Federal rules generally do not require notice to the general public or to neighbors of the areas sprayed.

Contrary to the assertions of some, there is no need for vast expertise to adopt important local rules to prevent local nuisances; local governments have been doing this for centuries. Thus, a Ph.D. in hydrodynamics is not needed to determine that signs should be posted on sprayed lawns warning parents of young kids of a recent pesticide application, nor is such expertise needed to determine that it is unwise to apply toxic materials above a town well field. How would we explain to the California parents, who were up in arms after a fog of phenoxy herbicides from an aerial spraying enveloped several school buses, that Congress has now prohibited local governments from reasonable actions to protect school children from such mishaps?

Federal preemption interferes with the important federal policy of local self-determination in these areas, and slashes at

the fabric of longstanding principles of federalism suggesting that the federal government should establish minimum national protections of the public, but that local police powers are preserved.

Finally, it important to point out that preemption is unnecessary. As noted earlier, any local rules adopted in the future that would conflict with state or local laws already would be preempted under standard constitutional principles. Local labels or packaging requirements also are preempted by FIFRA. No "inundation" by a supposed rising tide of burdensome or silly local rules will occur, because local authorities always have had the authority to adopt such rules and have been very circumspect in exercising that authority. Moreover, local governments are very representative of local constituencies, such as farmers, so no unwarranted rules are likely to ever be adopted. Lastly, it should be pointed out that the U.S. Constitution's Commerce Clause already prohibits state or local governments from adopting any rules that unduly interfere with interstate commerce. Thus, if, in the unlikely event that a local rule interfering with interstate commerce were adopted, the Courts could and would strike it down under the Commerce Clause. See, Philadelphia v. New Jersey, 437 U.S. 617 (1978).

Thus, despite the emotional calls for preemption, local government regulations have been reasonable and necessary, and preemption is absolutely unnecessary.

National Coalition Against the Misuse of Pesticides

701 E Street, SE, Suite 200 • Washington, DC 20003 • 202/543-5450



STATEMENT OF
JAY FELDMAN, EXECUTIVE DIRECTOR
NATIONAL COALITION AGAINST THE MISUSE OF PESTICIDES
BEFORE THE
SUBCOMMITTEE ON
DEPARTMENT OPERATIONS AND NUTRITION
COMMITTEE ON AGRICULTURE
U.S. HOUSE OF REPRESENTATIVES

JUNE 8, 1993

Mr. Chairman and members of the Subcommittee. I am Jay Feldman, Executive Director of the National Coalition Against the Misuse of Pesticides (NCAMP), a national, grassroots, membership organization, founded in 1981. NCAMP represents community-based organizations and a range of people seeking to improve protections from pesticides and promote alternative pest management strategies which reduce or eliminate a reliance on pesticides. Our membership spans the 50 states and groups around the world. Thank you for the opportunity to address the subcommittee today as a part of the process of working with you and the staff to address serious problems resulting from inadequate government regulation of pesticides and promotion of alternative methods of pest management.

Mr. Chairman, I would like to congratulate you again on your new position as chairman of the subcommittee. Given your active participation as a member of the subcommittee for many years, I know you are aware of the challenges that lie ahead and the most critical need for the subcommittee to address serious questions of health, safety and environmental protection. I share your concern for the farmer in the process of regulating pesticides on which they have come to depend. To that end, our organization looks forward to working with you and the Clinton administration to forge an alliance that will effectively move agriculture away from its dependency on toxic materials.

After working with the subcommittee for over a decade, I believe that we are now presented with an historical opportunity to break the logjam that has stalled health and safety reviews of pesticides and locked pest managers into pesticide-dependent management systems. The public and significant numbers of people in the pest management community, both farm and urban, will support an aggressive agenda that moves this country away from pesticide-dependent pest management and significantly reduces our country's reliance on toxic materials in the form of pesticides. We can do this with the

recognition that it will not happen overnight, but that it will happen soon. We can do this through the setting of a national goal of reducing pesticide reliance in pest management systems. And we can accomplish it with our country's ingenuity and spirit.

We face some pressures now that may appear painful and overwhelming to conventional chemical-intensive agriculture, namely the *Les v. Reilly* decision requiring the enforcement of the Delaney Clause and the loss of pesticides falling off the market as a result of reregistration (so-called "minor use" pesticides). Both these situations can and should be seen as opportunities for transition away from chemicals which most people say they would rather not use or be exposed to. There will be groups with vested interests who will staunchly defend current pesticide-dependent practices and resist the move away from pesticides. They will paint a picture of full knowledge about pesticide toxicity and exposure,¹ when this subcommittee has documented over the years the known risks and uncertainty that plague pesticide regulation, including the setting of acceptable risk and exposure levels.¹ There are those who will argue that the uncertainty surrounding many pesticide risks is justification for continued pesticide use rather than reason to curtail use in deference to the protection of user and consumer health and safety.

In the end, however, the pressure is mounting from different directions for pest managers to get off the pesticide treadmill. The public is now keenly aware of pesticide problems and has voiced its concerns through numerous polls and in testimony before this committee. In this climate, people will not accept a rollback in the protections of current law, either through a delayed reregistration, reduced testing requirements under the Federal Insecticide, Fungicide or Rodenticide Act (FIFRA), or reductions in protections provided by the Food, Drug and Cosmetic Act (FFDCA). Instead, we are calling for Congress and the Clinton administration to ensure that we meet the statutory goals of these laws by assigning necessary resources and priorities.

Over its twelve-year history, NCAMP has developed a broad, bipartisan coalition composed of those who have experienced the problems associated with pesticides and the benefits of alternative pest management practices that are not reliant on pesticides. People and their organizations that are a part of NCAMP come from both an urban and rural perspective, farm and nonfarm. What joins the coalition members together is a concern about the widespread use of pesticides that has resulted in adverse health and environmental effects

¹See *Lawn Care Pesticides: Reregistration Falls Further Behind and Exposure Effects Are Uncertain*, April 1993, GAO/RCED-93-80. This report indicates that EPA's reregistration is dangerously behind schedule, in some cases by as much as four years. The report paints a bleak picture of EPA review practices which may undermine the outcome of its reviews, issues which will be reviewed in detail later in this statement.

and property damage. These are not abstract problems, but real ones that demand government intervention.

Currently, chemical companies run roughshod over agricultural and consumer interests, characterizing the industry as a friend of the farmer and the consumer, but undercutting and abandoning them when they are damaged by their pesticide products. This situation is not new to farmers or homeowners who purchased pesticides or pesticide services with the belief that manufacturers had taken steps to ensure their customers' protection, only to find out later that the products had caused the contamination of their farm or home and threatened their family's health and welfare. Underlying farmer and consumer outrage over this situation is the misplaced trust that they put in government as a regulator of toxic materials and Congress, charged with oversight of the law and the implementing agency, the Environmental Protection Agency (EPA).

Now we are into the second half of 1993. We are still debating the pace of evaluating pesticide product safety. Deadlines imposed by 1988 amendments to FIFRA can not be met by EPA. The U.S. General Accounting Office (GAO) has documented a relaxation of data requirements in their April 1993 report. We are still hearing proposals, such as those put forth by some advocates of minor use pesticide relief, that would delay statutory requirements intended to get full health and safety and environmental fate information necessary for regulatory action.

I. Pesticide Dependency Is Increasing

We cannot take comfort in statements we often hear in this hearing room that pesticide use is going down, that less is being used and that we are therefore moving in the right direction. While this is true in certain areas and in certain crops, overall the trends show a disturbing increase in treated acres. According to Public Voice for Food and Health Policy's recently released report *Agrichemicals in America: Farmers' Reliance on Pesticides and Fertilizers*, "On a per acre basis, overall agrichemical use in U.S. agriculture has increased throughout the 1980s and early 1990s."² The report concludes that,

Different categories of agrichemicals have experienced different growth rates in the past decade: fungicide use has doubled, herbicide and fertilizer use has grown slowly, and insecticide use has remained stable following a decline in the early 1980s due to the banning of toxaphene.³

²Rosenfeld et al., *Agrichemicals in America: Farmers' Reliance on Pesticides and Fertilizers*, Public Voice for Food and Health Policy, May 1993, p. 6.

³Rosenfeld, p. 6.

Most disturbing is the fact that the percent of cropland treated with agricultural chemicals is on the rise. The numbers show a distinct trend toward increased dependency on pesticides in agricultural systems. "From 1969 through 1987, the percent of cropland treated with agricultural chemicals increased 131.3 percent for fungicides, 81.3 percent for herbicides, 58.4 percent for insecticides and 32.6 percent for chemical fertilizers,"⁴ according to Public Voice.

As our nation's agricultural dependency on pesticide increases on a treated acreage basis, we must ask if our national policy is moving agriculture in the right direction. FIFRA overall provides agricultural and urban pest managers with the wrong orientation, promoting pesticides instead of pest management, encouraging risk mitigation instead of pesticide minimization. Nevertheless, as the subcommittee tinkers with a fundamentally flawed statute, there have been attempts to bring pesticide law in line with the most basic environmental and public health protections, such as the 1988 amendments to FIFRA which established a pesticide reregistration, or reevaluation, timetable. At the same time, many proposals have circulated through and around the subcommittee which seek to reverse this movement through delays and weaker standards of protection.

II. Benlate Contamination: A Case in Point

Meanwhile, people are being harmed by these pesticides. Benlate contamination in Florida and 43 states is a situation that requires further investigation by this subcommittee, not only to provide assistance to at least 1,900 growers across the country, but to document the need for this subcommittee to move ahead forcefully and with determination to meet reregistration goals as set out in 1988. The focus should be on strengthening, not weakening, efforts at controlling pesticides, while providing assistance to transition pest managers away from pesticide dependency.

The Benlate problem began to surface in 1989, shortly after DuPont introduced a new formulation of an older product, whose sales had begun to decline. Benlate, which contains the fungicide benomyl, is designed to control fungus and mold. Growers who used the fungicide report that their crops were severely hurt (stunted growth and dieback) or wiped out. Farmworkers and farmers report adverse health effects. DuPont moved from a wettable powder (Benlate WP) to a dry flowable (Benlate DF), which is the consistency of sugar and more easily dissolved than the powder.

Originally, DuPont pointed to a weedkiller, atrazine, as the culprit in the losses, saying that the firm that processed the Benlate had allowed higher than the EPA-allowable "cross contamination" by not adequately cleaning its

⁴Rosenfeld, p. 4.

machinery. DuPont recalled the chemical in 1989, claiming that only a small portion of all the Benlate produced was contaminated. The company began marketing Benlate again until March 1991, when a second recall was initiated by the company. While growers thought it was another atrazine problem, DuPont, it appears, knew something else. However, at a December 4, 1992 meeting of the Florida pesticide Review Council, DuPont disavowed any culpability. This is after the company paid a reported \$500 million to farmers who had experienced losses. The payments were understood by growers to be partial payments - the real cost of property losses alone could reach the billions.

The active ingredient of Benlate, benomyl, is no stranger to controversy. The chemical was put in EPA's Special Review in 1977 due to findings that it caused sterility and birth defects in test animals. The chemical also has been shown to cause cancer in mice. In 1986, EPA concluded that benomyl should remain on the market with the proviso that users wear a paper mask. The agency concluded that the chemical was not easily absorbed through the skin and that a dust mask would protect workers.

Growers and workers exposed to Benlate have complained about muscle aches, fatigue, short- and long-term memory loss, joint swelling and pain, chest pains, nosebleeds, blurred vision, and other effects. Long term residual problems have also been reported. Greenhouse growers who have tried to replant after using Benlate have experienced continued contamination, even when old soil has been replaced.

Farmers challenging DuPont are joined by Florida Commissioner of Agriculture Bob Crawford. "If you believe Dupont's claim, then you must believe that 1,900 growers across the country simultaneously forgot how to recognize and take care of normal plant problems," said Dale Smith, a grower from south Florida.

DuPont says its study looked for effects from contaminants and breakdown products, effects from the so-called "inert" or secret ingredients, and effects from interactions with different formulations of the same product. It dismisses any possibility that one of the product's contaminants, butyl isocyanate (BIC), a relative of methyl isocyanate, which was associated with the 1984 Bhopal, India plant explosion and resulting devastation, is a factor. It dismisses the theory that sulfonyl ureas, contained in a DuPont herbicide, could have been mixed in the product as an impurity in the manufacturing or storage process. It rejects the idea that another contaminant, carbendazim, has been associated with nervous system effects. Other contaminants found in sampling includes the fungicide chlorthalonil and the fungicide flusilazole, which is not registered for use in the U.S. Aluminum has also been found.

In December, 1992, DuPont shared its own study findings with the

public, but not the underlying data. The study was conducted without government, victim or environmental group involvement. DuPont assembled its own "independent" panel of experts to oversee things. There is still considerable confusion as to whether DuPont has publicly released the complete list of inert ingredients. In U.S. District Court, March 15, 1993, DuPont was fined \$500,000 by the court for failing to release documents related to the company's investigation reports evaluating complaints about plant damage from the use of Benlate. The court based its order in part on a showing by the growers and nurserymen bringing the suit that expert reports, "according to the unchallenged testimony of DuPont's employees eliminated all other potential causes of plant damage other than Benlate."⁵

A Disaster Waiting to Happen. The Benlate disaster was a disaster waiting to happen. It raises serious questions about the adequacy of the pesticide registration and reregistration process, need for pesticide product efficacy and performance data, impurities policy, public disclosure of pesticide ingredients (including so-called "inert" ingredients) and quality control processes, and the auditing of pesticide testing facilities. The federal and state statutes governing pesticide registration and use have failed to offer the protection that people, including users and nonusers alike, expect and deserve. At the same time, EPA has failed to provide the guidance and the regulatory framework to ensure that pesticides will not cause harm.

The Benlate events have served to undermine the process of openness, right-to-know and full disclosure essential to public—farmer, farmworker and consumer— and environmental protection. Crucial to preventing future problems is full testing and disclosure of pesticide ingredients, including "inerts," contaminant and metabolites. Here, too, the public has a right to expect that some testing is completed and disclosed on the synergistic reactions between pesticides that are commonly used together.⁶ This information should not just be available after a crisis, but subject to public scrutiny and available

⁵*Bush Ranch, Inc. v. DuPont*, Civ. Action No. 92-34-COL, U.S. Dist. Ct., Middle Dist. GA, March 15, 1993.

⁶This is not a new suggestion to this subcommittee. In addition to NCAMP's previous advocacy for this, GAO testified in February 1992 in support of the need for evaluating synergistic effects. GAO said,

[N]ot considering synergistic effects contributes to uncertainty. Synergism occurs when the simultaneous action of separate substances—such as two or more active ingredients in a pesticide product—produces a greater total health effect than the sum of the individual ingredients. Generally, EPA does not assess synergistic effects because of scientific and cost limitations. [GAO, *Food Safety: Difficulties in Assessing Pesticide Risks and Benefits*, GAO/T-RCED-92-33, February 26, 1992, p. 5.]

through state and federal regulators prior to widespread use, or as the data becomes available on products undergoing reevaluation, or reregistration.

III. Reregistration Must Be Put on Track

The Benlate disaster raises serious questions about what is known about a widely used chemical and the questions that are asked by the regulatory review system. Benlate is, after all, one of hundreds of pesticides in reregistration. The failure of this review to move forward with all haste and the importance of reviewing the full battery of questions necessary to determinations of safety must be critical elements to EPA's program. Without either one of these elements, future disasters can be expected.

An April 1993 report issued by the U.S. General Accounting Office offers a very distressing update on the status of EPA's efforts at reregistration under the 1988 amendments to FIFRA. The report, *Lawn Care Pesticides: Reregistration Falls Further Behind and Exposure Effects Are Uncertain*, issues findings that indict EPA's program in two areas: (i) the failure to meet statutorily imposed deadlines; and, (ii) a reduction in data requirements as part of an effort to speed up the reregistration process. (GAO, in its report, cites EPA concurrence with the facts presented.)

To evaluate EPA's reregistration efforts, we must review EPA's evaluation in at least three areas of data: (i) **toxicity** (ii) **environmental fate**; and, (iii) **exposure**. GAO has described these areas in the following way:

- (1) toxicity data, generally from laboratory studies, to identify possible adverse health effects; (2) environmental fate and ecological effects data, which identify the fate of the chemical in the environment after application and its possible effects on nontarget species; (3) exposure data, which assess the frequency, extent, and routes of exposure for people, including subpopulations such as children.⁷

GAO found the following:

- *EPA is behind schedule on reregistration.* "EPA continues to fall behind its schedule to reregister the 18 major lawn care pesticides. In the meantime, the pesticides continue to be applied in large amounts without complete knowledge of their safety. Since March 1991, EPA's scheduled study completion dates for many of the 18 major lawn care pesticides have slipped significantly, some by as much as 4 years," according to GAO.⁸ The following contributed to delays, according to GAO: need for higher level studies; redoing

⁷GAO, April, 1993, p.11.

⁸GAO, April 1993, p.15.

rejected studies; time extensions; and, concern about pesticide derivatives. Much of the delay seems to be a function of the registrant failing to adequately perform a study and registrant delays resulting in time extensions. Some delays are generated by EPA.

The same can be said for food use pesticides, most of which are also used in lawn care. According to testimony delivered to the subcommittee in February, 1992,

Enactment of FIFRA '88 was intended to address such concerns [about the safety of many existing tolerances] by accelerating the reregistration of about 23,000 older pesticide products. However, the reregistration task has proven more formidable than anticipated, and EPA will not meet the 1997 reregistration time frame established by FIFRA '88. In the interim, previously registered pesticide products may be used on food under their existing registration and tolerances, despite EPA's incomplete knowledge of their human health and environmental effects.⁹

• *EPA has changed the basis of making reregistration decisions from "fully" complete to "substantially" complete data base.* Because of this change, it appears as though EPA has been able to accelerate its time schedule. In the case of 2,4-D, EPA eliminated the need for a crop residue study to make its reregistration decision, saving 21 months. With Isofenphos, the registrant made up 24 months in slippage when, "EPA determined that it did not need spray drift studies due in 1995," according to GAO. "Two other pesticides, Pendimethalin and Glyphosate, improved by 28 and 12 months, respectively, since June 1992, for similar reasons."¹⁰ EPA says it will be using data on similar pesticides when it drops a data requirement or will proceed with reregistration even though the study has not been received. According to GAO,

One of the 18 pesticides --Glyphosate-- is currently in Reregistration Eligibility Document (RED) preparation. Although EPA had earlier rejected a number of the registrant's environmental fate studies, it determined that the data base for Glyphosate was sufficiently complete with the studies. EPA officials told us that they may not require the registrants to repeat the rejected studies.¹¹

EPA told GAO that it might make registration decisions without waiting

⁹GAO, *Food Safety: Difficulties in Assessing Pesticide Risks and Benefits*, February 26, 1992, GAO/T-RCED-92-33, p. 6.

¹⁰GAO, April 1993, p.17.

¹¹GAO, April 1993, p. 17.

for a 1996 groundwater study on Diazinon or a cancer study on a Atrazine metabolite.

- *EPA does not have adequate exposure data to make safety decisions.* In its February testimony, GAO indicated that EPA did not have reliable data on the quantity of pesticides used on food crops. The statement went even further to say that inadequate knowledge supports risk estimates. According to GAO,

Our recent work on EPA's use of USDA's Nationwide Food Consumption Survey illustrates how inadequate knowledge may affect pesticide risk estimates. To establish safe levels of pesticide residues in or on food, EPA estimates dietary exposure to pesticide residues using data from USDA's survey, which is conducted every 10 years. However, we found that EPA's estimate of potential human exposure to pesticide residues in food is uncertain because these surveys are flawed. For example, our review of USDA's 1987-88 survey found that it was not representative of the U.S. population because the response rate was too low. To compensate for this deficiency, EPA is using the older 1977-78 survey data to estimate food consumption, but this survey may not reflect the current eating habits of Americans. Moreover, neither the 1977-78, nor the 1987-88 Nationwide Food Consumption Survey sampled subpopulations, such as infants and pregnant females, in numbers large enough to permit precise estimates of their dietary exposure and, hence, of risks to them from pesticide residues.¹²

Similarly, with nondietary exposure, EPA has poor exposure data to use for purposes of reregistration because the agency simply assumed that significant exposure was unlikely. However, the agency is in the process of rethinking the low exposure assumption. "In particular, they mentioned uncertainty about the persistence of lawn care pesticides in the environment and the amount of exposure received by children who, because of greater contact with treated areas, may receive more exposure than previously thought. . . EPA is working on better testing and assessment guidelines for all types of residential exposure to toxics," says GAO.¹³ It appears unlikely that EPA will have guidelines developed before FY 1997, if funding becomes available. And so, one of the critical elements of implementing a meaningful reregistration standard --exposure data-- is simply missing or wholly inadequate. GAO recommends that a pesticide "should not be reregistered for lawn uses unless EPA is confident that there is no health risk from exposure, especially to

¹²GAO, February, 1992, p. 7.

¹³GAO, April 1993, p.26.

children."¹⁴

Farmworker protection remains inadequate under new worker protection regulations that do not ensure that all workers have full information, training and medical monitoring provided all other workers protected under the Occupational Safety and Health Act. Our country's "harvest of shame" must be addressed within the context of reregistration to ensure the well-being of those who harvest the nation's food.¹⁵

• *Integrity of Test Data is Still an Issue.* The EPA Inspector General reported to the agency in 1991 of inadequate auditing of testing laboratories used by chemical companies that generate studies used for reregistration. We are not aware of any followup action resulting from this report that would ensure the public of the integrity of test data used for reregistration.¹⁶ GAO

¹⁴GAO, April 1993, p. 32. GAO says, "[U]ntil the new guidelines for conducting post-application exposure studies and risk assessments are developed, EPA will not know for certain how much exposure is associated with lawn care use of pesticides and what the subsequent health risks really are, especially for children."

¹⁵According to the GAO, *Hired Farmworkers: Health and Well-Being at Risk* (GAO/HRD-92-46), "Hired farmworkers are not adequately protected by federal laws, regulations and programs; therefore, their health and well-being are at risk. Hired farmworkers go into fields sprayed with pesticides, but many have no knowledge of the specific chemicals they are exposed to or the potential health effects. Field sanitation on many small farms may be inadequate, constituting a serious health hazard to hired farmworkers on those farms. Young children . . . may be more susceptible than adults to the harmful effects of pesticides."

¹⁶In the wake of major pesticide laboratory testing scandals involving falsified pesticide health and safety data, EPA's Office of the Inspector General (IG) has revealed serious gaps in the agency's Good Laboratory Practices (GLP) inspection program. According to the IG, EPA might not recognize a bad study when it came across one because, "The Agency does not have standards to determine if a specific GLP deficiency would compromise the validity of a study." According to the IG, "Of the 220,000 studies completed under FIFRA, only 2,268 have ever been audited - just under one percent." Since the program's inception, only 17 cases were pursued and penalties ranged from \$1,500 to \$30,000. The IG "believe[s] this low level of penalties gives the wrong message to industry - that the GLP Program is not a high priority, and no penalty, or a very small penalty, will result from not complying." When faulty or fraudulent data is identified, it does not affect the registration of the pesticide product in question. Instead, manufacturers are simply granted an extension to meet data requirements. [Kenneth A. Konz, Assistant Inspector

has similar concerns: "In our review of EPA's regulation of disinfectants, we found several weaknesses in EPA's data review, lab inspection, and data audit programs, which inhibited EPA's ability to ensure the quality and integrity of registrant-submitted data."¹⁷

• ***Resources Are Needed to Move the Reregistration Program Forward.***
As early as October, 1991, EPA testified before this subcommittee that it needed additional resources to meet the reregistration deadlines. In testimony before the subcommittee on October 30, 1991, Victor Kimm, then-Deputy Assistant Administration for Pesticides and Toxic Substances, said,

We have undertaken a long-range planning and scheduling process to determine the earliest feasible dates for assembling substantially complete data sets for each re-registration case. Based on this effort, we have also developed new cost estimates for re-registration, which have been shared with your staff. We project that a total of 366 (88%) of the re-registration cases will be Re-registration Eligibility Documents (REDs) by FY 97, including approximately 90% of all List A and B cases. Product re-registration decisions for all of the individually registered products in each case follows the RED by up to two years. Product re-registration simply verifies that a product complies with approved uses, has met the required data and label requirements, and contains no hazardous inerts; it does not evaluate risks. Based on this production schedule, and considering actual projected fee receipts and appropriate, we project a \$50 to \$55 million deficit for the re-registration program through FY 97.

At the time, EPA proposed a change in the maintenance fee caps collected from pesticide registrants, which requires legislative action. In addition to more aggressive enforcement of reregistration deadlines imposed on registrants, EPA needs adequate funding to move the reregistration forward.

IV. "Minor Use" Pesticides Represent Major Risks: Reregistraton Delays Unacceptable

We are five years into the FIFRA '88 reregistration program, behind schedule, and deficient in our nation's ability to protect against potentially dangerous exposure to pesticides. Yet, we are hearing the calls for further postponement of reregistration by forcing further delays for the so-called "minor use" pesticides. Instead of considering delaying already delayed

General for Audit, memorandum to Linda Fisher, Assistant Administrator for Pesticides and Toxic Substances, EPA, "EPA's Procedures to Ensure Quality Data Under the Good Laboratory Practices Program," September 30, 1991.]

¹⁷GAO, February, 1992, p. 13.

deadlines, we should be facing up to the challenge of finding alternative methods of pest management to replace the "minor use" pesticides. We have postponed regulating pesticides since 1972 when Congress first mandated reregistration with a 1976 completion date.

Economic Claim Unsubstantiated. The claim, of course, is that pesticides are being withdrawn from the market for economic reasons; that the registrants' costs associated with meeting health and safety testing requirements are not returned through the small volume of sales of these pesticides. However, this subcommittee has not to my knowledge ever received any economic data showing this to be the case. As a starting point, the subcommittee should have the data establishing need for addressing this problem. If Congress is to provide special consideration for "minor use", as we address below, then it should have data that supports the need for this special consideration. This is true because there are alternative theories as to why "minor use" pesticides are being withdrawn from the market.

Minor Crops Are High Exposure Crops. An alternative theory that may explain, in large part, why "minor use" pesticides are being withdrawn from the market was presented to the subcommittee in March 1992. At that time, NCAMP explained that the "minor crops" are also the highest exposure crops both to hand labor and in terms of dietary exposure. EPA's description of action taken in 1991 on parathion describe the high exposure associated with minor crops.¹⁸

¹⁸Consider EPA's September 5, 1991 settlement agreement on parathion, in which the agency determined that risks to agricultural workers in "field crops" are lower than fruit and vegetable crops. According to EPA, "Parathion is one of the most acutely toxic pesticides registered by EPA." In its press release on this highly toxic insecticide, the agency said,

EPA has determined that risks to agricultural workers associated with parathion use on the nine field crops -- alfalfa, barley, canola, corn, cotton, sorghum, soybeans, sunflower and wheat -- are lower than for other crops such as fruits and vegetables because of mechanical harvesting rather than hand labor.

The pesticide registrant voluntarily withdrew all use on fruit, nut and vegetable crops. In a question and answer piece, the agency said,

For example, field crops are generally harvested mechanically, not hand-picked like many fruits and vegetables. Mechanical harvesting generally involves less risk for exposure to fieldworkers. Furthermore, the registrants have agreed to place a number of added restrictions on the use of parathion on field crops. The application of parathion under the strict protective requirements included in the settlement agreement pose

The subcommittee has a large amount of testimony on the subject. The testimony establishes the fact that "minor" crops represent major exposure. James Wells, Director of the Department of Pesticide Regulation for the California Environmental Protection Agency testified in February 1992 that,

"Minor" crops are in fact "major" to California —they include virtually all fruit, nut and vegetable commodities. For example, in 1990, 14 of the 15 highest value crops grown in California were minor use crops, representing 89% of the total value of the top 15 crops.¹⁹

Another witness at the same hearing, Ray William, Professor and Extension Horticultural Weed Specialist with Oregon State University Extension Service, testified that,

Nearly all crops grown in the Pacific Northwest are considered minor-use with respect to pesticide registration. . .Crop diversity and farmer ingenuity produce an array of specialty products for a health conscious America. Oregon's horticulture is valued at \$1.8 billion for processed or wholesale products, providing employment for numerous citizens. Horticultural commodities include fruits, nuts, vegetables, berries, nursery crops, hazelnuts, vegetable seed, and several hundred other specialty crops.²⁰

And yet another witness, Madeline Mellinger, president of Glades Crop Care of Florida told the subcommittee that,

The minor use problem is severe in a state such as Florida, with over

the least amount of risk of exposure to agricultural workers.

Under the agreement, hand-harvesting of treated crops is prohibited in addition to other use restrictions. And so, the minor uses of this highly toxic pesticide were finally voluntarily cancelled after decades of evidence and EPA staff calling for its demise in 1988. The point is that "minor uses" and high human exposure correlate highly.

¹⁹James Wells, Director, Department of Pesticide Regulation, California Environmental Protection Agency, Testimony before Subcommittee on Department Operations, Research and Foreign Agriculture, Committee on Agriculture, U.S. Congress, February 19, 1992, p. 8.

²⁰Ray William, Processor and Extension Horticultural Weed Specialist, Oregon State University Extension Service, Testimony before Subcommittee on Department Operations, Research and Foreign Agriculture, Committee on Agriculture, U.S. Congress, February 19, 1992, p. 1.

150 vegetable and fruit crops. . .Also, let's remember that these crops should also be a significant part of the diet, especially among children.²¹

Minor crops are also the biggest users of pesticides on a per acre percentage basis. According to Public Voice, "Fruit and vegetable operations remain by far the most reliant on agrichemicals despite a leveling off of aggregate insecticide use per acre on U.S. farms since the early 1980s."²² The report continues,

Fruits and vegetables comprised all but one (96%) of the top 25 commodities treated with the highest pounds per acre of active insecticide ingredients for the 1987-1989 period. Pears were ranked number one, averaging 68.2 pounds per acre of active ingredients. Nectarines, apples and citrus ranked second, third and fourth respectively, each treated with more than 25 pounds per acre of active insecticide ingredients. Other fruits and vegetables ranked in the top 25 include: Plums, peaches, apricots, olives, cherries, brussels sprouts, melons, strawberries, celery, cauliflower, grapes, cranberries, artichokes, cabbage, lettuce, collards, dates, sweet peppers, broccoli and raspberries. Their application amounts ranged from 20.9 pounds per acre of active ingredients to 3.9 pounds. Almonds were the only crop other than fruits and vegetables in the top 25.²³

Resistance Management Argument for "Minor Use" Pesticides Flawed. Some maintain that "minor use" pesticides should be retained in order avoid pesticide resistance problems that are attributed to sole reliance on an individual pesticide. In fact, pest resistance has been shown in arthropods, plant pathogens and weeds going back to 1908 (Holt and LeBaron, 1990) and is not a new phenomenon attributable to the "minor use" problem. While presenting the subcommittee with the resistance argument for continued "minor use" registrations, Patrick Weddle, President, Weddle, Hansen & Associates, of Placerville, CA, testified in February, 1992 that,

Alternatives to chemical miticides and other conventional chemicals do exist, but they require an implementation infrastructure that is not widely available. I refer you to my testimony before this committee on March 1, 1990 for a further discussion of the need to move towards the development and expansion of IPM infrastructure. Unless and until

²¹Madeline Mellinger, President, Glades Crop Care, Florida, Testimony before Subcommittee on Department Operations, Research and Foreign Agriculture, Committee on Agriculture, U.S. Congress, February 19, 1992, p. 4.

²²Rosenfeld, p. 6.

²³Rosenfeld, p. 27.

alternatives to conventional pesticides are forthcoming, growers must be allowed to protect their crops. Knowledge of an interim "grace period" prior to cancellation will encourage growers, commodity leaders and crop protection researchers to plan and develop an orderly transition towards alternatives.²⁴

There is no evidence that a "grace period" will lead to the development of alternatives without a concerted and directed effort tied to the phase out of these chemicals. Many seem to agree that EPA and USDA need to engage in a cooperative effort to assist in identifying new crops and more diverse rotations and generally assist in the transition to sustainable agricultural approaches that are not reliant on pesticides.

Continued Reliance on "Minor Use" Pesticides Will Undermine Alternatives. GAO identified the vicious cycle that continues through FIFRA to undermine the interests of farmers who are now dependent on "minor use" pesticides, as the agency ignores alternatives. According to GAO,

Specifically, we found that EPA lacks reliable data on the quantity of pesticides used on food crops and, more importantly, the effect of various pest control alternatives on crop yields. In the absence of reliable data, the agency pieces together whatever information it can on a case-by-case basis from a variety of sources, including reports from USDA and state agriculture departments and pesticide manufacturers, scientific literature, commercial survey, and estimates of experts and farmers. The problem is particularly acute for estimates of less frequently used pesticides or for pesticides used on smaller-volume crops, such as fruits and vegetables. We concluded that, currently, EPA's benefit assessments are not meeting their full potential to help refine the agency's regulatory decisions primarily because of limitations in the data used.²⁵

Action for Pesticides in Reregistration Whose Uses Are Voluntarily Cancelled. NCAMP supports a "minor use" program that finds alternative pesticide management approaches, rather than one that simply postpones the inevitable cancellation of a pesticide —only to force another decision point further down the road, with no progress toward the development of alternative pest management options. NCAMP suggests a minor use program, if established, should conform to at least the following:

²⁴Patrick Weddle, President, Weddle, Hansen & Associates, Placerville, CA, Testimony before Subcommittee on Department Operations, Research and Foreign Agriculture, Committee on Agriculture, U.S. Congress, February 19, 1992, p. 7.

²⁵GAO, February, 1992, p. 8.

1. In cases where growers would like to see a voluntarily withdrawn pesticide retained, the reason for the pesticide's withdrawal from the market should be determined with findings of fact;
2. If it can be determined that the pesticide is being withdrawn for purely economic reasons and there is no evidence to suggest that this pesticide would not meet reregistration standards either because of farmer, farmworker or dietary exposure or environmental effects, the pesticide should be considered for public assistance. Interim restrictions, pending reregistration, should be imposed to protect against unknown risks due to toxicity, exposure or environmental effects;
3. A special fee should be assessed the registrant which would partially cover costs associated with reregistration, and public funds would cover the balance of the costs;
4. Product efficacy and performance data should be made available;
5. There should be a showing that the particular pest management goal(s) cannot be realized through nonchemical or lower toxicity methods, thus ensuring that alternatives are not currently available; and,
6. At the same time, the use of this program should trigger pest management research to address the defined pest or cropping problem.

V. Alternatives Must Be Integrated in Regulatory Process

When EPA announced its proposed "Incentives for Development and Registration of Reduced Risk Pesticides,"²⁶ it offered the public two potentially conflicting messages, one seeking to eliminate pesticide dependency and other aimed at "mitigating risks." The first promotes safer alternative pest management practices, the second promotes potentially less toxic inputs into conventional pesticide intensive practices. One is pest management, the other is pesticide management. Pest management strategies do not necessarily include pesticides as a component. Pesticide management strategies do. We can ask the question of whether we can reduce or mitigate risks associated with pesticide use, or we can ask the more basic question of whether we need pesticides to meet our pest management goals. The question we ought to be asking through a policy of this sort is whether any range of risks associated with any level of toxic pesticide use are necessary risks.

²⁶"Incentives for Development and Registration of Reduced Risk Pesticides," 57 FR 32140.

As we face pesticide problems, we can no longer simply talk about substituting toxic chemicals with chemicals of lower toxicity. We must talk about REPLACING toxic materials with pest management approaches that are not reliant on poisons. For example, some herbicides dubbed "safer" because they are used in such small quantities that residues are not detectable, are potent enough to cause damage to non-target organisms. Every pesticide, even a "safe" pesticide poses ecological risks from instability of natural enemy populations, secondary pest infestation, non-target impacts, and resistance.

We have experienced the chemicalization of agriculture and urban pest management in the last several decades as a result of impressive marketing by chemical manufacturers. We are now reaping the adverse effects of this chemical revolution. Groundwater contamination is ominous. Studies show elevated rates of cancer in farmers who use pesticides, among children living in homes where pesticides are used, and in pets living in households where lawns are treated with pesticides. Parkinson's disease has been linked to pesticide use and increasingly pesticides are shown to disrupt the nervous and immune systems.

We can no longer assume the benefits of pesticides when the same pest management goals can be reasonably achieved with less risk. In fact, we believe that a true reading of FIFRA would make it a violation to allow the use of a toxic material when the same "benefits" can be achieved with less risk.

Under a sound federal pesticide policy, the law must, in our view, concern itself with practices or the methods of pest management. Let's take agriculture. When we look at agriculture, we must first consider "production systems that rely, to the maximum extent possible, on biological processes, and the interrelationships of biological processes, within nature, to achieve agricultural goals." That, by the way, is also the definition of organic agriculture, according to Fred Kirshenmann, organic farmer from ND and president of Organic Foods Production Association of North America (OFPANA). He also quotes Lampkin (1990, p. 6) who says that organic agriculture "concentrates primarily on adjustments within the farm and farming system, in particular rotations and appropriate manure management and cultivation, to achieve an acceptable level of output. External inputs are generally adjuncts or supplements to this management of internal features." "[O]rganic agriculture. . . is absolutely dependent upon maintaining ecological balance and developing biological processes to this optimum. The preservation of soil structure, earthworms, microorganisms and larger insects is essential to the working of an organic system. Therefore, the protection of the soil and the environment is a fundamental "must" for the organic farmer and not something that can be tacked on at the end if profits allow."

This is the framework for the discussion, whether we are talking about

agricultural or urban pest management. EPA should set as a national goal for pesticide registration the minimization of pesticide use while meeting pest management goals. The goal is to prevent risk outcomes, not try to establish lower risk outcomes – If we as a nation seek as a national goal lower risk, we may well institutionalize unnecessary risks in the process. FIFRA must embrace the most basic public health principle –prevention. It not reasonable to allow risk, when you can prevent it.

We must break with the past adherence to proposals and practices which, in effect, sought to minimize pesticide restrictions or minimizing impact on current pesticide use patterns. However, rather than moving to a system that advocates replacement pesticides, public policy must effectively minimize pesticide use.

There are at least three elements that must be addressed in sound pesticide policy: (i) moving pest management beyond its current dependence on chemical treatments; (ii) defining a sound process for identifying when and where control of pests is needed; and (iii) restructuring the registration and reregistration program so that it is firmly rooted in pest management concepts.

Conclusion

Pesticide policy must encourage a reduction in the reliance on pesticides, whether in the farm or urban context. If this is a goal, then our policies have failed miserably. The trends in increasing percentage of acreage treated with agrichemicals shows the long steady march toward pesticide dependency. We have an important opportunity to reverse these trends through FIFRA and related research policy.

Appendix

A Federal Pest Management Act Is Needed

It is the purpose of the federal pest management act to provide for the protection of public health and the environment from unwise or inappropriate pest management practices. It is founded on the notion that the environment and natural resources of the country are a heritage which is held in trust for the benefit of succeeding generations and that the public health is a paramount concern, not subject or subordinate to economic considerations. The approach is founded on the belief that a just and effective regulatory scheme cannot be devised, established, or administered without public understanding and involvement.

In keeping with the purpose, the act has the following goals:

- (i) adopt and implement a national and international policy for the promotion of integrated pest management and sustainable natural resource management;
- (ii) recognize that pesticides are toxic substances and that they must be regulated as part of a cradle-to-grave toxics control policy;
- (iii) govern pest management practices by a regulatory scheme that embodies open decision making and public participation at every stage and at all levels;
- (iv) govern pest management practices by a regulatory scheme that is health-based and designed to protect all susceptible populations; and
- (v) ensure that environmental quality must not be degraded and shall be protected by the promotion of safe pest management practices and by eliminating dependency on chemical pest management and agricultural methods.

Establish a program for eliminating chemical dependency. The first and foremost goal of the act is the weaning of pest managers from their chemical dependency. The pesticide regulatory program is embedded in a pest management framework. Currently, public policy dealing with pest management strongly encourages reliance on chemical fixes. In order to correct the current course of public policy, in addition to strong controls on pesticides (discussed below), a new program of education and incentive to implement *best available least toxic* alternatives is needed.

Elements include the following:

- In three years, all pesticides become restricted use, unavailable to general use without training and certification.
- In five years, no registration continues without identified need, with a showing that there are not alternative approaches that could be used.
- Establish incentive for state programs that promote sustainable agriculture and minimize pesticide use, e.g., tie to state grants.

- Act should be made self-funding through registration fees or extensive sales/excise tax, with progressive increases for those products for which research on alternatives is needed.
- Demonstration grants for applied research, demonstration and education of low pesticide management of pests in urban settings.
- Development of an expert system for all common urban pests and alternative treatment methods made available to country governments and other local outlets.
- Training for real estate, building management, and lawn and grounds treatment in low or no pesticide alternative management schemes for pests.
- Areas under the Clean Air Act and Clean Water non-point pollution sections will be required to develop alternative no pesticide management plans, with federal funds related to clean air, sewage plant construction and other federal grants bearing upon environmental quality tied to the adoption of these plans.
- Anything funded by the federal government must use alternatives to pesticides.
- Federal loans at lower rate for nonchemical farmers, accompanied by federal crop insurance.
- Repeal pesticide exemptions in all federal laws.
- Shift jurisdiction of environment and public health portions of law to committees of Congress that oversee these issues.

Establish a process for identifying pest control needs. A survey must be conducted to identify for a site, pest problems requiring intervention and known possibilities for addressing them. The *best available least toxic* alternative(s) should be identified for these sites. Every several years, or whenever the agency receives a petition claiming that a *best available least toxic* alternative exists, the process should be repeated. The process should be public in order to include those who will bear the impact of the decision.

Regulate pesticides in the pest management context. Based on the pest control needs established, pesticide regulation must be approached with a cradle-to-grave orientation. The risks associated with pesticides begin when they are manufactured and continue until they are decomposed into harmless constituents. Before imposing risks on people and the environment, all

possible poisoning and contamination related to the pesticide must be evaluated.

Elements include:

- All ingredients of the pesticide formulation must be thoroughly tested for all potentially significant health and environmental effects through all possible routes of exposure, including, but not limited to: acute, chronic, cancer, reproduction development, neurotoxicity, immunotoxicity, cumulative and synergistic effects.
- Cradle to grave controls must be established: (i) an exposure assessment must identify all possible routes of exposure; (ii) it must be determined that the product and residues may be disposed of safely; (iii) degradation pathways must be documented; and, (iv) clean-up methods for accidental releases must be available.
- It must be determined that use is essential prior to registration or reregistration of a product before the product may be sold. This determination involves the following: (i) thorough testing of complete formulation, metabolites, and degradation products; (ii) a determination of how much the chemical will leach under conditions of use and reasonably foreseeable misuse and illegal use; (iii) determination of synergistic effects with other chemicals with similar use patterns; (iv) determination that the product meets the need for which it is to be registered, taking into account resistance and prohibiting purely cosmetic uses; (v) a public decision making procedure allowing preregistration access to data for public and considers all alternatives, all impacts, and all reasonable comments; (vi) the manufacturer must disclose practical analytical detection methods that can quantify residues of the product and its degradation products in air, water, soil, plants, and animal tissue; (vii) pesticide registrations sunset in 3 years, while any person or company may petition EPA to begin a second year sunset period immediately in view of the fact that less toxic alternatives are available to control the same pests with less health and environmental risk; (viii) tolerances will be set at levels that protect the most sensitive segments of the population, while no exposure will be permitted for pesticides or their residues or byproducts that cause cancer, birth defects, mutations, reproductive effects, or alter the immune system or behavior of non-target organisms, and no tolerance will be set for any pesticide that is not registered for use in the U.S., and no exemptions from tolerances will be granted.
- A permit shall be required to use restricted use pesticides, with users being trained and certified. Pesticides cannot be used as a preventive measure, rather the pest problem must be evident.

- Only pest control advisors, who have no conflict of interest may issue a permit for application of restricted use pesticides. A permit may be obtained to use a restricted use pesticide only when its use is essential to avoid greater risk, considering all alternatives.
- Enforcement may be accomplished through federal enforcement action, state enforcement action or citizen suits against violators. The user, prescriber, and manufacturer of a pesticide shall be subject to strict joint and several liability for injury arising from its use. If special registrations are allowed to be granted by states, states become potentially liable.
- EPA will collect statistics on (i) usage —chemical, type of use, target, and (ii) impacts on humans and the environment. Usage statistics will be required of all certified applicators, and all dealers will be required to submit sales data. Physicians will be required to report all cases of pesticide poisoning. A pesticide incident monitoring system will be established to allow citizens to report problems arising from pesticide use. State agencies involved in pesticide research and enforcement will be required to report all adverse impacts and these reporting mechanism will be used in registration decisions to determine the real impact of pesticide use.
- All pesticides shall be classified as "restricted use" unless EPA finds that: (i) the pesticide is sold in small quantities (sufficient to treat no more than 1/10 acre); (ii) application methods have minimal impact; (iii) all testing has been completed; (iv) the pesticide has limited adverse effects if used according to the label and taking into account reasonably foreseeable misuse; (v) the pesticide is classified in the minimal risk category in three classifications (a) acute toxicity; (b) chronic toxicity; and, (c) environmental toxicity and/or fate (leaching, tendency to drift) or manufacturing concerns (worker exposure to toxic ingredients, disposal, and waste).
- Full public notification of pesticide use prior to use.
- The EPA administrator may cancel the registration of a pesticide, modify the registration of a pesticide, or require changes in a pesticide label by issuing a rule subject to public comment and appeal procedures.
- When a pesticide registration is cancelled, existing stocks of the pesticide may not be used under existing pesticide label, but will be relabelled if the new standard allows or disposed of at the manufacturer's expense using the most environmentally sound method available.

- Ban production and export of pesticides that cannot be legally used in this country.

We urge the committee to consider true reform of FIFRA with a federal pest management act. The goal is *pest* management, not *pesticide* management. With this in mind, a true debate is required if we are to stop the further deterioration of our land, air, and water from unnecessary pesticide use.

Testimony Submitted to the
Subcommittee on Department Operations and Nutrition

House Committee on Agriculture
U.S. House of Representatives

Prepared by

Richard Wiles
Director, Agricultural Pollution Prevention Project

Kenneth A. Cook
Vice President for Policy

Christopher Campbell
Research Assistant

June 8, 1993

Mr. Chairman, distinguished members of the Subcommittee. Thank you for the invitation to testify today on the subject of pesticide registration, reregistration, and related matters.

I am Richard Wiles, director of the agricultural pollution prevention project at the Center for Resource Economics, a nonprofit environmental research organization based here in Washington, D.C. I am presenting testimony today on behalf of my colleagues at the Center, Kenneth Cook and Christopher Campbell.

Reducing risks posed by pesticides to human health and to the environment is a priority at the Center. Before joining the CRE staff, I served as project officer for several pesticide policy studies conducted by committees of the Board on Agriculture of the National Research Council (NRC). The first such study produced the 1987 report, *Regulating Pesticides in Food: The Delaney Paradox* (National Academy Press). I also served as the original project officer for the forthcoming National Academy study that will examine methodologies for assessing the risks posed to infants and children by pesticide residues in the food supply.

The scope of today's hearing embraces many of the core issues that face Congress as it reauthorizes the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and revises the Federal Food, Drug and Cosmetic Act (FFDCA). We look forward to working the you, Mr. Chairman, and with other members of this

subcommittee in the months ahead on the full range of FIFRA reauthorization issues.

Recent research at the Center has focused on several topics that relate directly to the subjects of today's hearing. Of particular relevance is a report that we are now finalizing on pesticide residue levels detected in fruits and vegetables that are consumed in large quantities by infants and by children under 5 years of age.

Using data obtained under the Federal Freedom of Information Act and from other sources, we have constructed databases comprised of detailed estimates of food consumption in the U.S. population, and the results of pesticide residue tests conducted between 1990 and 1992 on over 20,000 samples of food.

Our report, to be released later this month, will analyze patterns of infant and child exposure to a variety of pesticides in the food and water. We will also present estimates of the cancer risk to young children that is associated with those patterns of dietary exposure.

Today's Testimony

Our testimony focuses on two interrelated observations that arise from our research. We offer them as a point of departure for the subcommittee as it takes up FIFRA reform.

First, our research indicates that the U.S. population, and young children in particular, are being exposed to low-levels of pesticides in the food supply with far greater frequency than previously recognized.

Second, if the weight of evidence does suggest that children exhibit special sensitivity to pesticides and other toxins, even at low levels, then the exposure patterns that we have found raise important public health questions for pesticide policy, including registration and reregistration.

These observations do not justify abrupt and immediate changes in personal eating habits. We do believe, however, that they justify major and fundamental changes in pesticide policy in order to reduce systematically the real, albeit chronic risks posed to children by low levels of pesticides in the food supply.

Low-Level Dietary Exposure To Pesticides: More Prevalent Than Previously Recognized

Dietary exposure levels from pesticides constitute a central issue in pesticide registration and reregistration. The setting of tolerances that protect the public health is, after all, one of the primary goals of the entire reregistration process. In setting tolerances, EPA takes into account the toxicity of a pesticide and human exposure to the pesticide, which is a function of the frequency and level of the pesticide's occurrence in foods. Determinations of exposure are

especially important for "minor use" crops—a distinctly misleading term, we might note. Crops that are "minor use" in terms of acreage treated are often "major league" in other respects, notably in volume of pesticides applied; the magnitude of infant and child consumption; the extent of worker exposure and the extent to which farmers now rely on high toxicity pesticides for pest control.

Our analysis of test data from commercial laboratories indicates that pesticides occur in many fresh fruits and vegetables with considerably greater frequency than the Food and Drug Administration (FDA) has found and reported in the past.

It is our understanding that the Department of Agriculture is soon to release its 1992 report for the Pesticide Data Program, and that the report will reinforce our analysis of pesticide residue data from commercial laboratories. That is, because of improvements in testing protocols, USDA will report substantially higher occurrences of pesticide residues in food than the Department reported for its first analysis, for 1991. Today we are submitting a Freedom of Information Act request to USDA for the complete set of data for both 1991 and 1992.

For the most part, pesticide residues are detected at levels well below established tolerances. The question then becomes: are existing tolerances for pesticides adequate to protect the public health? In particular, based on the best available evidence, are existing tolerances adequate to safeguard the health of subgroups in the population that may exhibit special sensitivity to pesticides and other toxins?

As you develop amendments to FIFRA, Mr. Chairman, we recommend that the Committee review emerging information from our study and from the USDA Pesticide Data Program, regarding the occurrence of pesticides in the food supply. This information, we submit, should be reviewed against the backdrop of the National Academy's report on methodologies for assessing risks to children from toxins, including pesticides.

Conclusions

It is our view that a new framework for pesticide policy will emerge in the coming months as a result of a deeper scientific understanding of the risks of pesticides in the food supply. That framework is built on emerging information about the prevalence of low levels of pesticide residues in the food supply; a clearer understanding of food consumption patterns, especially among infants and young children; and emerging scientific understanding about the risks that pesticides and other toxins in food may pose to young children and other sensitive subgroups of the population.

Among the implications of this new framework are the following:

- Pesticide tolerances will have to be lowered significantly for many compounds in order to protect public health.

- A number of pesticides likely will have to be phased out, as the risk they present in the food supply or in drinking water is too great to perpetuate their usage.

- EPA will increase program efficiency and provide greater benefits to farmers and the public health by focusing limited reregistration resources on crops that present the greatest overall risk.

**TESTIMONY OF
JAY VROOM, PRESIDENT
NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION**

**BEFORE THE UNITED STATES HOUSE OF REPRESENTATIVES
COMMITTEE ON AGRICULTURE**

SUBCOMMITTEE ON DEPARTMENT OPERATIONS AND NUTRITION

JUNE 8, 1993

The National Agricultural Chemicals Association (NACA) is pleased to have the opportunity to present the following comments to the Subcommittee on several important issues related to the regulation of pesticides in the U.S. under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). NACA is the not-for-profit trade organization of U.S. manufacturers, formulators and distributors of agricultural crop protection and pest control products. Our membership is composed of the companies that produce, sell and distribute virtually all the active compounds used in crop protection chemicals registered for use in the United States.

These comments will focus on eight areas in which recent legislative proposals or regulatory developments will have a profound impact on NACA's members: product registration, reregistration, benefits consideration, minor use, cancellation, suspension, international harmonization, and preemption. We in agriculture understand the important role which pesticides have played in the production of food and fibre and prevention of disease throughout the world. However, we have occasionally failed to communicate to the public the amazing amount of scientific expertise and staggering financial commitment that goes into each of our products. Therefore, these comments will highlight NACA's position with respect to various proposals, and the innovative ways in which we are working with EPA.

NEW PRODUCT REGISTRATION

In today's rapidly changing and competitive marketplace, the agricultural chemical industry must be responsive. NACA's members are constantly focusing on new markets and products, and investing in new technologies. As a result, an impressive array of new packaging designs are now or will soon be available -- from closed container systems and water soluble packaging to pesticides formulated into tablets and gels -- resulting in fewer containers and less overall waste. New delivery systems are improving on-target application performance. These impressive developments are the result of our commitment to invest in the future of American agriculture.

However, one of the single most important investment our members make is in the research and development of new active ingredients. Collectively the pesticide industry commits about \$800 million **per year** to research and develop products for the U.S. market - which equates to approximately 10 - 12% of annual sales. Registration of a new product takes from 7 to 10 years, costs up to \$50 million, and can require up to 120 separate scientific tests. That's an enormous investment in our future, and in the future of agriculture.

Although we work closely and have established good communication with EPA, our biggest frustration is still the time it takes to get a new product registered. With the amount of money invested, we simply cannot continue to wait several years for a registration. To address that concern, some have proposed a "fast track" for certain so-called "reduced risk" products. While that proposal may have some initial appeal, we believe it is important to expedite all new product registrations. It would be unfair to bog down the system further by putting a select, arbitrary group of products ahead of others, even further delaying their

review and registration. Before creating a new "fast track," we must first fix the track we've got.

The time required to bring a new crop protection chemical to market -- and its ability to produce and protect the food supply -- also has profound implications for our ability to continue to feed an exploding population. The latest UN figures for world population growth show that we have to feed a new city the size of Paris every ten days, and an extra population the size of Germany every nine months. Yet even now we are failing miserably to feed the existing population. Some 30,000 children die each day from malnutrition and preventable disease. Clearly, the development and use of new agricultural chemicals must become a more near-term endeavor if we are to continue to feed the world.

Over the past decade, America's farmers have managed to produce the vast majority of the world's fresh fruits and vegetables, seed and grain, while using fewer agricultural chemicals. Data from NACA's U.S. Industry Profile studies have shown that the total pounds of pesticide active ingredients sold declined from 947,718,000 in 1979 to 863,582,000 in 1992. Nevertheless, the observation has been made that because mandatory government programs in three northern European countries (Denmark, Sweden and the Netherlands) have resulted in decreased pesticide use, the U.S. should adopt a similar program. However, this suggestion ignores the American farmers' unique position and responsibility in world agriculture, and the discretion which they have shown in their use of pesticides. It also does not consider the vastly different climates and destructive crop pests and diseases faced by American farmers. Our farmers deserve congratulations, not mandatory reduction programs.

NACA is committed to working with EPA to find new ways to streamline the registration process without compromising safety or scientific standards. For instance, open

dialogue between industry and the government eventually resulted in EPA's decision not to require aquatic and avian tests for every new product. The elimination of time consuming testing requirements -- which neither compromised public health or safety, nor resulted in useful data -- avoids unnecessary registration decision delays. Through improved agency/industry communication, NACA hopes to further improve the speed of new product registration. In a field as complex and dynamic as pesticides, it's imperative that EPA maintain frequent and open dialogue with registrants. Unless all sides understand what is expected of each other, new product registration can eventually grind to a halt.

In the past few years, we have been able to establish a good dialogue with policy officials in the Office of Pesticide Programs concerning many regulatory and funding issues, allowing NACA and EPA to better understand each others' expectations. Although we have certainly had our differences, we have also been able to address some problems before they have become unmanageable. We are confident that Administrator Browner and her team will keep an open door policy at EPA, and we look forward to working with her on FIFRA and related food safety issues.

REREGISTRATION OF EXISTING PESTICIDES

The speed of EPA's reregistration program has come under increasing public criticism as it has become clear that the 1997 deadline for reregistration of all active ingredients registered and their formulated products on the market before 1984 would not be met. NACA is also concerned about delayed reregistrations, not because of any public health or safety risk, but because of the public misperception that the agency is not doing a good job of regulating our products.

NACA supports the goals of reregistration, and we compliment the agency on the new structures and management activities, and a willingness to listen to our concerns. As

the decisions made and data submitted months ago works its way through the review process, we expect that this year alone several important, major food use active ingredients will have completed reregistration. We are hopeful that by 1997 all major food uses will have been reregistered, and that reregistration for other pesticides can be completed shortly thereafter.

We are very concerned, however, that even as the number of products to be reregistered continues to decrease, the cost of the reregistration program continues to grow. While certain fixed costs cannot be avoided, it seems only logical that some savings could be realized as the size of the program and units of "production" decreases. For that reason, combined with a lack of a precise accounting of the areas where additional fees are needed, EPA's recently projected \$20 million program shortfall is extremely troubling.

Nevertheless, NACA continues to honor the fee structures put in place through FIFRA '88 and its amendments. As you know, pesticide registrants have already born a sizeable share of the financial responsibility for the reregistration program. Since 1988 the pesticide industry has contributed \$92 million dollars through a combination of one time active ingredient fees and annual maintenance fees for each product. Currently, maintenance fees alone amount to approximately \$15 million per year. Additional user fees alone cannot possibly solve the enormous problems created by a combination of Congress-provided public appropriation funding cuts, increasing costs, and an increasing number of program demands placed upon EPA. As new sources of revenue are discussed, we must also honestly address the need to fully fund existing programs, realistically assess the impact of additional demands on the current reregistration program, and demand accountability from all participants, government and industry alike.

One way EPA is working particularly hard to speed the reregistration process is

through its soon-to-be-completed "rejection rate" analysis. With the cooperation of NACA members, in 1991 EPA began to examine the rate of study rejection for residue chemistry, environmental fate, ecological effects, non-dietary exposure and toxicology tests. Historically, 30 percent of reregistration studies submitted by manufacturers for agency review have been deemed unacceptable. In many cases, multi-year studies were rejected late in the process and required to be redone for reasons which could (and should) have been clearly defined before the study was begun. EPA estimates that the cost, to industry, for repeating the rejected studies ranged from \$600 million to \$1.2 billion; the costs to EPA in terms of administrative expense and public confidence have also been very high. In all, between 150 and 250 product reregistrations will likely be delayed by an average of two years.

While not yet completed, as a result of the "rejection rate" analysis, EPA and NACA member scientists have already identified several important common rejection factors. In addition, the criteria for EPA evaluation of industry studies are better defined, the studies submitted for EPA review more precisely match EPA criteria, and dramatically faster reregistration decisions will be made. NACA applauds EPA for this effort, and we look forward to similar, successful, joint projects in the future.

BENEFITS

Pesticides are a necessary and vital component of modern production agriculture, public health maintenance and disease control. The benefits of pesticide use has been repeatedly shown through countless examples of entire crops saved from mold, rot and pestilence, and of countries rid of certain insect born diseases. For instance, in many parts of the world in which malaria killed and disabled large portions of the population, that disease has all but disappeared. In the southeastern United States, yields of peanut crops

would drop by 68% and aflatoxin content would increase, without the use of fungicides to control foliar and seed diseases.

However, the issue in the legislative debate over benefits is not whether pesticides have benefits, but rather how benefits are used to determine whether certain risks are acceptable, and as to how the marketplace may evaluate one product against another, or one product as against another technology. As part of the registration process, current law properly provides for the evaluation of the risks and benefits of a pesticide. A fair evaluation of any risk necessarily includes an assessment of the benefit to be derived from acceptance of the risk. However, recent legislation proposed by Congressman Waxman and Senator Kennedy would eliminate the benefits side of the current equation, making the granting of a pesticide tolerance a "risk-only" decision. We believe that proposal to be ill-advised.

The main misconception which clouds the debate over benefits consideration is that by conducting a risk-benefit analysis, EPA will somehow focus only on benefits, and regularly ignore prudent concerns as to risk. After decades of registration decisions and pesticide use, the evidence simply does not support such a belief. While some continue to argue for a risk-free approach to pesticide regulation, science and human experience teach us that such a result is impossible to achieve without losing many products and completely destroying our current agricultural economy. In fact, exhaustive Agency consideration of benefits usually occurs only in the carefully scrutinized special review process: EPA "bases initial tolerance and registration decisions primarily on perceived risks to health and environmental considerations...the principal role of benefit analysis is to inform EPA decision makers *during special review*...about the extent of the benefits associated with a specific pesticide's use." (GAO Report, EPA's Use of Benefit Assessment in Regulating

Pesticides, March 7, 1991). (Emphasis added.) Consequently, it would be virtually impossible for EPA to simply ignore prudent concerns about risk.

NACA believes that confidence in the current risk-benefit standard could be increased by a clear articulation of the kinds of benefits data EPA needs to make its decisions, and development of better information on use patterns (beyond the major crops) with respect to particular pesticides. More accurate and complete information on pesticide usage would also help restore public confidence, and allow risk-benefit decisions to be made more easily.

MINOR USE

An unfortunate consequence of the high cost of reregistration has been the loss of several thousand pesticide registrations. Shortly after the annual maintenance fees were first assessed, registrants began voluntarily dropping the registrations for those products whose sales could no longer justify the increased fees and testing costs. Since the reregistration program began in 1989, nearly one-half of some 40,000 formulated product registrations have been voluntarily dropped. Of those, most were registered in name only -- they were not actually being produced or sold. However, many of those registrations were for use on so-called "minor" crops, which became victims of market forces and economies of scale which left their registration economically impractical.

Recognizing the potential for disruption, NACA established a Board-level task force to address the issue. In addition, an interim fax communication network was set up in 1991 to give users and growers advance notice of uses which would no longer be supported by the registrant. A person at each company familiar with the registration slated for cancellation was designated to act as a central point of contact to interact with growers. This program acted to bridge the information gap, and did so until USDA's National Agricultural Pesticide

Assessment Program ("NAPIAP") was up and running. Although it didn't solve the minor use problem, we are pleased that we were able to provide the growers, EPA and others fast and accurate information at a time when it was needed.

Today, NACA continues to monitor the minor use problem, and explore ways to fashion creative, effective solutions. For instance, NACA is an active participant in USDA's Minor Use Working Group, and we have supported several workshops (along with USDA, IR-4 and growers) to educate others on procedures necessary for third-party registrations. NACA also commends both the efforts of the Minor Crop Farmers' Alliance, and the principles of the legislation provided in H.R. 967 by Mr. de la Garza. This is a difficult problem in that the market does not justify the cost of retaining certain registrations, and the deadlines for reregistration are unforgiving. NACA is, however, committed to assisting in the development of a workable solution, and will remain an active participant in the process.

CANCELLATION

There is some concern that the amount of time required to cancel a product's registration under existing law is far too long. To a large degree, NACA agrees with that concern. We think that this process can and should be shortened, and would support reasonable changes to streamline and improve the process. However, in improving current law, it is critical that the procedural and substantive due process rights of the registrants not be jeopardized, and that the significant consequences to farmers and others who depend upon access to these products not be ignored.

In an effort to shorten the process, NACA would support reasonable time limits in the formal rule making proceeding. The time for cancellation could be significantly shortened, while still allowing for specialized input from USDA and independent experts

such as the Scientific Advisory Panel (SAP). Specifically, NACA believes that the cancellation process could be completed within one year, and would support that legislatively. However, an essential element of the shortened hearing process and loss of "special reviews" must be the right to conduct cross-examination. In fairness to the manufacturers, and the general public, pesticide cancellation must include due process, wider participation, and a complete investigation of the facts.

A pesticide's registration is extremely important to the users whose businesses depend upon access to those products. In addition to agriculture, those users include urban pest control, disinfectant and sanitation industries, rights-of-way maintenance companies, floral and nursery growers, and many others. Because so many people and business depend upon these products, it is important to ensure that the debate which accompanies a cancellation proceeding be firmly rooted in scientific fact, and not reduced to emotion or hyperbole. Consequently, the procedures used to conduct a cancellation proceeding must be designed to elicit the most reliable information, in a reasonably short amount of time.

SUSPENSION

Quite separate and apart from cancellation, FIFRA's suspension provisions were originally conceived as a way to quickly remove a product from the market in the event of a true emergency. Some recent proposals to amend FIFRA's cancellation provisions have also included amendments to the suspension provisions. One particular proposal would even have allowed pesticides to be banned in non-emergency situations. Referred to generically as "interim-suspension," such proposals lack scientific/health based justification, and would cause havoc for the agricultural chemical industry and the farmers who rely on those crop protection products.

When faced with an "imminent hazard," current EPA authority is enormous. In

addition to an outright seizure, EPA can immediately "suspend" a product's registration for continued sale and use. As a result, EPA may quickly and effectively remove the product from commerce, and prevent further use, all prior to holding a hearing. This legislative authority allows EPA to act immediately to protect the public health from any emergency threat.

Those who advocate changing the standard for initiation of a suspension proceeding have not pointed to any credible evidence to support a change to current law. As the time required to cancel a registration decreases, the rationale for changing the trigger or standard for suspension evaporates. Consequently, to the degree that public perception demands some sort of revision, the far most appropriate response is the streamlined cancellation procedure described above.

INTERNATIONAL HARMONIZATION

In order to encourage high global standards and consistency in the scientific evaluation of its products, NACA strongly supports efforts aimed toward the international harmonization of testing protocols and data reviews for pesticide chemicals. Since 1971, the 24 countries participating in the Organization for Economic Cooperation and Development (OECD) have produced approximately 85 protocols which serve as the basis for accepting studies for the review of chemicals. In 1991, the OECD began to focus specifically on additional protocols necessary for review of pesticide chemicals. With the active participation of U.S. EPA staff, significant progress has already been made in two areas.

One uniquely successful effort involves the comparison of pesticide data reviews, in order to identify similarities and differences in the way countries evaluate the same data. The goal of this pilot project is to determine whether there are sufficient similarities in the review of data so that in the future it may be possible for one country to accept reviews

performed by others. NACA supports this effort because the already high standards for review utilized in the United States will increasingly become the standard elsewhere, while at the same time the need to perform expensive and largely redundant separate data reviews in each OECD country of registration will decrease.

A second important project is underway which will create new, and revise the old OECD testing protocols for the review of pesticide specific chemicals. Just two weeks ago, the ruling body of the OECD approved the first of the new guidelines. EPA's commitment to participate in both of these projects will pay large dividends for the agency and the American public. NACA strongly encourages their continued participation, and supports other such efforts at harmonization, including encouraging EPA to coordinate its pesticide residue tolerances with the CODEX Alimentarius, as suggested in HR 1627, the Lehman/Bliley/Rowland bill.

There is broad legislative and regulatory interest in these efforts because the development and review of separate tests and protocols in each country is extremely costly. It is obviously in everyone's best interest to coordinate and cooperate as early in the process as possible.

PREEMPTION

Uniformity of pesticide use regulation is another major concern to NACA. In July of 1991, the U.S. Supreme Court found that Congress had not made explicitly clear its intent to preempt some 80,000 units of local government from independently regulating the use of pesticides. We understand that legislation will soon be introduced by Congressmen Volkmer and Smith (similar to legislation adopted by the DORFA Subcommittee in the last Congress) which will clarify the original preemptive intent of Congress.

Under FIFRA, pesticides may be registered only by State and Federal governments.

Consequently, existing authority provides sufficient protection and opportunity for regulation. Adding regulation by local governments -- yet a third governmental body -- would not increase the quality or efficiency of existing regulation. Instead, 83,000 different sets of ordinances would result in conflicting and overlapping regulation, and general public confusion.

CONCLUSION

In closing, I wish to thank you again for this opportunity to share NACA's views on various FIFRA-related areas. The agricultural chemicals industry looks forward to working with this Subcommittee to create positive, meaningful changes to FIFRA.

(Attachment follows:)

How Do We Test for Safety of Food?

by F. J. Francis
University of Massachusetts, Amherst

How do we know what foods are safe to eat? Primitive people were forced to rely on personal experience. If they or their families ate something and got sick or died, that food was definitely not on the menu for the next meal. Today, food toxicologists use laboratory animals to determine the relative safety of our food, so we're spared the painful necessity of conducting personal tests.

Food safety can be divided into two major areas: that concerned with microorganisms in food and the area concerned with chemicals in food. This paper is concerned with chemicals that may be found in our food supply.

Test Candidates

What foods and food compounds do toxicologists test for safety? The candidates fall into four main categories. The first includes compounds found in natural products. Literally hundreds of compounds produced by nature are dangerous for people to ingest. This group includes alkaloids in some mushrooms and toxins in some shellfish. Compounds added to food for specific purposes (intentional or direct food additives) make up the second major group. Examples are antioxidants to prevent oils from going rancid, preservatives to prevent food from spoiling, and colorants to make food more appealing. Indirect or incidental additives are a third major group of substances derived from packaging materials as well as the pesticides, antibiotics, hormones, and other chemicals used to control pests and to promote better health and growth of crops and animals. The residues of these indirect additives may find their way into human food. The fourth and final group is environmental pollutants, such as lead, cadmium, mercury, or certain phenols.

Animal Models

Rats and mice are common test subjects, but sometimes chick embryos, rabbits, dogs, monkeys, fish, and other species are employed. The best gauge of human risk comes from animals that metabolize the test substance in a manner similar to humans.

What happens when a food or chemical is fed to animals? The effects range from no observable response, to benefits, to unfavorable results, or death of the animal, depending on the nature and quantity of the substance ingested. The responses range from gross effects, such as a change in tissues that are observed microscopically, to biochemical changes, such as enzyme activity that are measured analytically in the laboratory.

Figure 1 illustrates four classes of responses. It shows how the animal response is plotted against the dose. Responses plotted above that corresponding to zero dose are accepted as adverse effects. Responses plotted below that corresponding to zero dose are beneficial effects.

In Figure 1A, the compound has no observable effect on the particular response being measured within the dose range tested. A compound such as starch would show this response.

In Figure 1B, there is no threshold, and an infinitesimally small dose elicits an unfavorable response. This response class

is hypothetical, and its existence is hotly disputed among scientists. Labeled the "one-molecule hypothesis" by some, it is embraced by others, who argue that there is no safe dose of cancer-causing (carcinogenic) substances. Although the existence or nonexistence of this class of responses is theoretically subject to experimental verification, the appropriate experiments have never been done, and they are not likely to be done. The reason is that infinitely large numbers of test animals are required to measure the effects of infinitely small doses.

In Figure 1C, there is a "threshold" dosage below which there is no observable adverse effect. Most compounds are in this category. A threshold exists because people and animals can detoxify, metabolize, or excrete small amounts of almost any substance. At higher doses, the ability of the animal to handle the compound is exceeded, with adverse effects.

In Figure 1D, there is a range in which addition of the compound has a beneficial effect leading to an optimum level that is followed by a range with an adverse effect. Essential nutrients, such as vitamin D and selenium, are in this category, but the classic example is oxygen.

The Threshold Level

Before a company can introduce a compound into the food supply, it must test the compound for safety. In the basic experiment, test animals (generally rats or mice) receive different amounts of the compound in their diet.

Figure 2 illustrates the results of a typical feeding experiment using compound X. The horizontal axis shows the doses of compound X fed daily to separate groups of animals under otherwise similar conditions. Included in the experimental series are a "control" group with zero dosage of the compound and three groups with different known doses. The measured values are indicated by the experimental points on the graph.

The next step is to determine mathematically the maximum daily dose above the control at which the response is zero or the same as the control. Names for this dose include the threshold level, no-effect level, no-observed-effect level, and no-observed-adverse-effect level (NOAEL).

The Acceptable Daily Intake

The threshold or no-effect level is divided by a safety factor to obtain the "acceptable daily intake" (ADI). The ADI is usually expressed as milligrams of the test substance per kilogram of body weight per day, using the ratio of dose to body weight

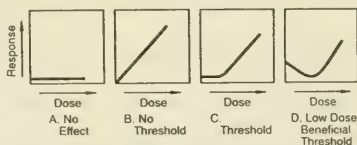


Figure 1. Four types of responses to increasing doses of a substance being tested in the diet of animals (Francis, 1986).

Dr. FJ Francis, Uof Mass - Amherst

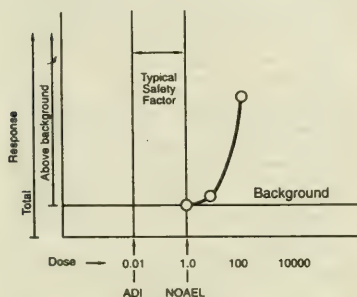


Figure 2. The results of a typical experiment in which four similar groups of test animals are fed different doses of a substance proposed for use as a food additive (Food Safety Council, 1982). ADI = acceptable daily intake; NOAEL = no observed adverse effect level.

on the responses. If doses were expressed as milligrams per animal, one might expect to find, for example, that a lethal dose for a mouse would be below the no-effect level for an elephant.

Expressing the doses as intake per day rather than per lifetime takes into account the fact that the normal lifetime varies greatly among species. Expressing the intake in units per day implies that the responses are more nearly a function of the dose per day than the dose per lifetime.

The magnitude of the safety factor used to derive the ADI from the no-effect level is arbitrary. It may vary according to the circumstances as assessed by toxicologists. The "standard" value is 100. The rationale for using 100 is that if the average sensitivity of humans to compound X is 10 times greater than that of the test animals, and if the most sensitive humans are 10 times as sensitive as the average, dividing the no-effect level by a safety factor of 100 (10×10) would assure that the most sensitive humans could still safely ingest a quantity of substance X equivalent to the ADI.

One More Step

There is one more step—determining the concentration of substance X to allow in food. Because the ADI is a quantity and the allowable levels in foods is a concentration, a quantity of food must be selected as a basis for calculating the allowable concentration. The Food and Drug Administration estimates the probable intake of food containing the additive in question and uses this as a basis for calculating the allowable concentration. If the quantity of the additive needed for the food or foods in question is less than the ADI, the additive may be approved later for use in other foods until the total amount estimated to be ingested in all foods is equal to the ADI.

When the final allowable concentration is determined in this way, the result is bound to be an approximation for any given person since individuals decide for themselves how much food

they will eat and what their diet will be. This approximation, however, has not been a cause for significant concern, and the procedure described, with use of a safety factor of 100 in establishing the ADI, has a long and reassuringly successful history.

Compounds That Cause Cancer (Carcinogens)

The 100-fold safety factor described in the preceding section is not suitable for carcinogens for three reasons. First, the order of magnitude is much greater—up to 5,000 instead of 100. Second, with humans, there could be a lag factor of 20 years or more. Third, some investigators do not believe that a threshold or tolerance level exists. In addition, five concepts introduce uncertainties into the calculations, namely: (1) choice of animal model, (2) mode of exposure, (3) level of dosage, (4) method of extrapolation from high doses to low doses, and (5) need for extrapolation of the data from animals to humans. Because of these uncertainties, the usual procedure in the past has been to adopt a very conservative approach, but all of the above assumptions have been severely criticized in recent years.

Choice of animals. The choice of animal model has created uncertainties because of the variation among species. Even among the same species, for example with mice, sensitivity could vary by as much as a factor of six. Another example is dioxin, a contaminant in Agent Orange used to defoliate the jungles in Vietnam, which received the dubious designation as the Darth Vader of the environmental movement because of its extreme sensitivity. The LD_{50} (the amount which causes the death of 50% of the treated group, in terms of micrograms per kilogram of body weight) was one for the guinea pig, 45 for female rats, and 5000 for hamsters, respectively. Obviously, the choice of the guinea pig as the model of choice is a very conservative approach.

Mode of exposure. The preferred mode of exposure is that which matches as closely as possible the route of human exposure whether by ingestion of food or water, inhalation, skin exposure, or injection. Ingestion in food is the most popular, but free access to food by rats results in fat rats, which are more susceptible to cancer.

Level of dosage. The level of dosage is probably the most controversial. A standard bioassay is performed on both sexes of animals at three dose levels plus a control. Thus with 50 animals in each group of rats, a total of 800 animals is required. The dose levels are usually the "maximum tolerated dose" (MTD), 1/2 of the MTD, and 1/4 of the MTD. The use of the MTD has been criticized because it causes cell proliferation (mitogenesis) and rapidly dividing cells are more susceptible to mutations (mutagenesis). In turn, mutating cells are more susceptible to production of tumors (carcinogenesis). Critics have charged that the MTD is too high and in itself causes cancer. The decision as to whether a compound is carcinogenic or not should not be based on effects at the MTD level.

Extrapolation. The method of extrapolation from high to low dosages is equally controversial. Test animals have to be fed a large dose of the compound in question in order to demonstrate an effect with a reasonable number of animals. If the dosage is too low, the experiment simply does not generate any

data. But with large dosages one hopes that the effects will be similar at low dosages. This apparently is not usually true since the body has a very efficient repair mechanism. Assuming that the experiment uses large doses, then the problem becomes one of how do we extrapolate the curve for laboratory data down to the real world which involves very small doses. The extrapolation can be very large—up to 10,000 times—and the simplest way is to just draw a straight line from the last data point down to the concentrations found in the real environment. This has been criticized because of the body's repair capacity, but assuming we do use a straight-line extrapolation, statistically there can be an upper and lower limit. Previous calculations of risk have used the upper line (worst case scenario) but this leads to a large overestimate of risk. A middle-of-the-road interpretation is more acceptable.

The ability to predict human cancers from data on animals is clearly a judgment call but the odds improve as we learn more about the underlying mechanism of cancer causes and progression. To date, all chemicals known to cause cancer in humans also cause cancer in animals with the possible exception of arsenic. But the reverse prediction does not appear to hold. There are hundreds of compounds classified as animal carcinogens but it has not been possible to establish that they also cause human cancer. Examples are saccharin, cyclamate, and DDT. To date, of the 54 known human carcinogens, evidence of carcinogenicity was first obtained in animal studies in only 8 of them. The rate of prediction of human carcinogens from animal data is obviously very low. However in support of animal data, if a compound produces similar results in several animal species, it is likely that the effect is a basic aspect of metabolism common to most animals including humans. For example, aflatoxin (a toxin produced by a fungus that can grow on peanuts, corn kernels, and a number of other cereals and nuts) is carcinogenic in mice, rats, fish, donkeys, turkeys, marmosets, tree shrews, and monkeys. It should be no surprise that it is also carcinogenic in humans. But not all examples are as clear-cut as this one. The National Cancer Institute tested 190 chemicals on rats and mice; 44 were positive in both rats and mice; 58 were positive in either rats or mice. Clearly there is a species difference, and the experimenter may be in the unenviable position of having to decide whether a human is more like a rat or a mouse. Obviously these anomalies will be minimized as our knowledge of the physiology of tumor production increases. But the choice of an appropriate animal model should be tempered with its relevance to humans.

The Delaney Clause

The uncertainties inherent in the decision as to whether a compound is carcinogenic or not has complicated another aspect of food safety. In the 1950s, U.S. Representative James J. Delaney held a series of legislative hearings and asked a panel of toxicologists if they could predict whether a compound would cause cancer in humans. They said, "No" in many cases. He then asked whether they could tell at what concentration a suspect compound would cause cancer. Again, they said, "No!" Representative Delaney then wrote into the 1958 food safety

laws the famous Delaney Clause, which states simply that no compound which causes cancer should be added to our food. That clause served us well for over thirty years, but today it is hopelessly obsolete. The main reason is the amazing increase in the sensitivity of analysis. In the early 1900s, analysts could detect milligram quantities of impurities (10^{-3}). Around 1950, the limit had fallen to microgram amounts (10^{-6}). In the 1970s, the detection limits were decreased to nanogram quantities (10^{-9}). In the same era, picogram (10^{-12}) quantities could be detected easily. With extensive clean-up and optimization, the limits could be pushed to femtogram (10^{-15}) quantities. Lately, papers have appeared in the literature reporting analyses at attogram (10^{-18}) levels. Perhaps the ultimate to date is the claim that High Performance Capillary Electrophoresis (HPCE) is capable of detecting milliattograms (10^{-21}). Since Avogadro's number is 6×10^{23} molecules per mole, this sensitivity is pushing the analysis to the molecular level.

Obviously, there is no way that animal experimentation for carcinogenicity can cope with the infinitesimally small quantities that the analytical chemists are capable of finding. The question for interpretation of risk is not "Is the compound present?" but rather "What does it mean?" In the 1950s, approximately 50 carcinogens were recognized and they could be easily regulated by existing food safety laws. Today, with the definition of carcinogens described in this paper, there are several thousand.

Other Approaches for Safety Testing

Epidemiology is the science that attempts to determine the pattern of human disease by studying the relationship between factors that are suspected to be causative agents. Simply put, it attempts to determine the difference between a group exposed to a given compound or condition and a group which has not been exposed. Epidemiology may be able to identify the association between events which may be risk factors, but it cannot usually determine cause and effect.

Epidemiological studies can be very useful. For example, cigarette smoking, alcohol, and radiation are known causes of cancer. Epidemiological studies were able to identify 14 more chemicals and industrial processes associated with human cancer, and 40 more probable causes. Studies on the proportion of cancer deaths in the U.S. due to various factors listed diet at 35% and tobacco at 30%. Infections, reproductive and sexual behavior, occupation, geophysical factors, and pollution were listed at 10, 7, 4, 3, and 2% respectively. The epidemiological approach was used to determine the carcinogenic risks of compounds in food. Surprisingly, 98% of the risk of carcinogens in food was due to the natural components of food. Clearly, epidemiological studies are not subject to the vagaries of animal testing and can be very useful. But they only apply to compounds or events that have been in our environment for some time—they are after the fact.

A number of procedures have been developed to partially or completely replace animal tests. These include microbiological tests, tissue culture, plants, chick embryos, fish, computer simulations, and structure determinations. One of the best known

short-term tests is the "Ames Test." It depends on the ability of a compound to cause mutagenesis in microorganisms, on the assumption that mutagenicity and carcinogenicity are highly correlated. More recent research involving a wider spectrum of compounds has shown a much lower correlation between the two. The battery of short-term tests is useful but unlikely to replace animal testing in the near future.

Summary

The use of animal tests to determine safety in foods has been universally successful and accepted around the world. Essentially the level on the diet which exerts no-observed-effect level (NOEL) is determined. This level, when divided by 100 (to produce a 100-fold safety factor), becomes the level of acceptable daily intake (ADI). The procedure works very well for compounds that do not produce cancer (noncarcinogens) but not for compounds suspected of causing cancer in humans. There are three main reasons: (1) the safety factor may be much larger, up to 5,000 instead of 100; (2) the lag factor may be much longer, up to 20 years or more; and (3) some investigators do not believe that a tolerance or threshold level for some compounds exists. Regardless, animal testing for carcinogens will continue because there is no readily acceptable substitute. But there may be some changes in interpretation. These include the abandonment of the maximum tolerated dose (MTD), better choices for methods of extrapolating from high to low doses, and more appropriate choices of animal models. All of these will be improved by a better understanding of the physiology of human cancer.

The determination of safety is complicated by another factor. The Delaney Clause in food legislation states that no compounds that cause cancer can be added to foods. Advances in analytical chemistry have made this clause obsolete.

Suggested Reading

1. Francis, F. J. 1992. *Food Safety: The Interpretation of Risk*. Council For Agricultural Science and Technology, Ames, Iowa.
2. Kraybill, H. F. and L. T. Flynn. 1990. *From Mice to Men: The Benefits and Limitations of Animal Testing in Predicting Human Cancer Risks*. American Council on Science and Health, New York.

3. Hall, R. L. 1985. Safe at the plate. *Science of Food and Agriculture* 3(1):11-17.

Literature Cited

- Food Safety Council. 1982. *A proposed food safety evaluation process*. Final report of the board of trustees. Nutrition Foundation, Washington, D.C. 142 pp.
- Francis, F. J. 1986. Testing for toxicity. *Science of Food and Agriculture* 4(2):10-14.

Naturally Occurring Toxicants and Nutrients

The safety factor of 100 is used for most substances proposed for addition to foods, but Mother Nature's additives ignore the rule. The foods we consume contain many naturally occurring toxicants that have been found safe as a result of consuming the foods containing them without ill effects. As noted in a previous article (1), however, the safety margins for some naturally occurring toxicants may be far less than the safety factors applied for compounds proposed for addition to foods. For example, solanine, an alkaloid found in potatoes, may be consumed in amounts equivalent to as much as one-seventh of the no effect level, yet we can eat potatoes without concern for an effect of this toxicant.

The 100-fold safety factor is not used for essential nutrients because this would not be consistent with the known requirements of these substances for satisfying nutritional needs and maintaining health. As pointed out by the chief of the Food and Drug Administration's Food Additive Evaluation Branch, "Toxicity may be reached for some essential nutrients, for example, vitamin A, vitamin D, certain essential amino acids, [and] iron, at levels less than 10 times higher than those recommended for optimal nutrition. Substances that serve as sources of energy for man obviously cannot be fitted into the constraints of a 100-fold safety factor."

1. R. L. Hall. 1985. Safe at the plate. *Science of Food and Agriculture* 3(1):11-17.

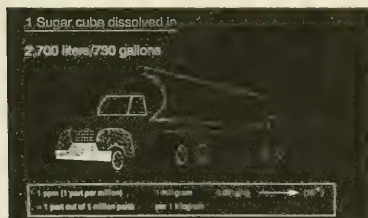


Figure 3. Illustration of the meaning of parts per million (ppm). Illustration courtesy of the author.

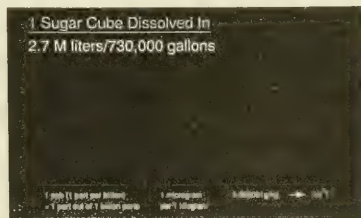


Figure 4. Illustration of the meaning of parts per billion (ppb). Illustration courtesy of the author.

TESTIMONY OF RALPH ENGEL

PRESIDENT

CHEMICAL SPECIALTIES MANUFACTURERS ASSOCIATION

BEFORE THE

SUBCOMMITTEE ON DEPARTMENT OPERATIONS & NUTRITION

UNITED STATES HOUSE OF REPRESENTATIVES

JUNE 8, 1993

Good morning, my name is Ralph Engel. I am President of the Chemical Specialties Manufacturers Association (CSMA) located at 1913 Eye Street, NW, Washington, D.C.

CSMA has a membership of some 440 firms engaged in the manufacture, formulation, distribution and sale of pesticides, antimicrobial products, automotive chemicals, detergents and cleaning compounds and polishes and floor finishes for household, institutional and industrial use. A significant number of these products have pesticidal claims and are therefore subject to EPA jurisdiction pursuant to the requirements of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

Specifically, CSMA represents the nonagricultural pesticide industry, including disinfectants and sanitizers, home, lawn and garden pesticides and a wide variety of pesticides for home, industrial and institutional use.

The Registration Process

Mr. Chairman, the Subcommittee is precisely on target in examining the EPA pesticide registration process. The Environmental Protection Agency (EPA) under the FIFRA, is charged with the dual responsibility of protecting human health and the environment and registering pesticides for general use, restricted use or both. As we have repeatedly testified before this Subcommittee, the registration system administered by the EPA is not working and it is time that this Subcommittee exercise its oversight responsibility to see to it that the Agency properly administers this program and is held accountable.

Subcommittee members should understand that the granting of a federal EPA pesticide registration is only the first step in the marketing of a pesticide product. Subsequent to obtaining a federal registration, manufacturers and formulators of pesticides must also obtain a registration in each state before each product can be sold.

The consequences of a malfunctioning federal registration program are far reaching because the definition of a pesticide under FIFRA is extremely broad and encompasses many products such as antimicrobials as well as home and garden products (toilet bowl cleaners, bleach, wasp or hornet spray) if

these products bear pesticidal label claims. The inability of American business to market numbers of products adversely affects the economy and the ability of the business community to provide jobs. The Subcommittee should understand that this is a management problem and not an issue of compliance with environmental requirements under FIFRA.

President Clinton has made it clear that environmental regulations which promote gridlock and impede the economy with little or no benefit are to be eliminated. The EPA registration system is a perfect example of that gridlock.

The registration program is the single most burdensome process which EPA administers. It adversely affects the ability of manufacturers and formulators to enter the market and compete. It imposes such unreasonable delays on applicants for pesticide registrations that they cannot compete with other firms and are denied the opportunity to even introduce identical or similar products (me-too products) to compete with those already on the market, let alone to develop a new active ingredient.

We estimate that the problems related to the registration system account for many millions of dollars per year in lost or delayed sales. Companies which have made enormous investments in product research and development, stymied by the Agency's inability to make decisions, receive no return on their investment. In addition, ancillary sales functions related to the development and marketing of pesticide products are affected. For instance, the introduction of new or improved consumer, industrial and institutional pesticide products would account for increased productivity in the

manufacture of containers, and an increase in the services required for their distribution.

Let me emphasize that while we firmly believe that reform of the EPA registration process is essential, CSMA is not seeking changes which would compromise thorough scientific review or the public health. On the contrary, the paralysis within the registration process is frequently denying the availability of products with significant public health benefits, while adversely affecting the pesticide industry, with an enormous value (\$8.26 Billion Annual Sales) to the American economy.

The system should be revised to institute procedures to avoid bottlenecks; presently a simple administrative procedure takes months to complete holding up registrations for no valid reason. An example is an affirmation by a registrant that it will make the EPA mandated label changes on its new labels yet, registrants often wait months for a letter back from EPA giving them permission to proceed with the printing of new labels and granting a registration. There is no need for this process to continue; a certification by a registrant that it has complied with the EPA mandated label language should be sufficient to permit the issuance of the registration and the production and marketing of the pesticide product.

In addition to specific suggestions for modification of the existing registration procedures which will be set forth in detail below, we suggest that there are a few immediate steps which this Subcommittee could take to begin the process of evaluation of the current registration system and to move toward an improved, less cumbersome, but still responsible registration

posture. In particular, we suggest that:

1. Provisions be written into FIFRA legislation which will require EPA to contract with appropriate outside management personnel to conduct a thorough examination of the registration and reregistration process and to make recommendations in a report to Congress as to how to specifically improve program performance and meet the 1997 statutory deadline.
2. Statutory language should mandate that EPA forward the contractor report to this Subcommittee within nine months of the letting of such contract.
3. Statutory language should be contained in legislation directing the Administrator to report the status of the registration system backlog on a bi-annual basis to this Subcommittee.

Antimicrobials

For too long the fate of antimicrobial products has been caught up in the registration morass because they are included in the definition of pesticides in FIFRA. These products have non-food uses such as disinfectants used in hospitals, institutions, health care facilities and homes and provide benefits for maintaining the public health . For instance, in the aftermath of Hurricane Andrew, some of the most sought after products to help survivors were insect repellents, bleaches and disinfectants. The public does not understand that products such as a toilet bowl cleaner or even a bleach are pesticides and hence subject to the EPA registration process. Improvements in these products are often prevented for years because of improper and

unnecessary delays.

The problems of the EPA registration system are amply illustrated by noting that it has been many years since a new active antimicrobial ingredient has been registered. One of our member firms has advised us that it has had a pending application for a new antimicrobial active ingredient in the EPA system for nearly seven years but that such application is sitting in limbo within the registration process. Just as importantly, marketers of formulated, end-use, antimicrobial pesticide products with ample resources to conduct the necessary studies on the end-use formulations and with aggressive marketing organizations have been forced to sit on the sidelines for months or years awaiting an EPA approval, even for a me-too product.

It is apparent that major changes in FIFRA need to be enacted to address the antimicrobial product area:

1. We believe that the Subcommittee should separate and distinguish antimicrobials from other pesticides and streamline the regulatory process for them, by establishing an Office of Antimicrobial Programs.
2. The Subcommittee should consider and develop a separate statutory definition for antimicrobials distinct from pesticides but within FIFRA jurisdiction.

With the establishment of this dedicated EPA function and separate statutory definition, registration applications could enter the system correctly and be handled by appropriate designated personnel. This would speed up the process within the Agency and would permit the more precise accounting

of funds, thus assisting this Subcommittee in its oversight function.

CSMA is presently participating with several other associations in a coalition to bring to this Subcommittee suggested changes with respect to the registration of antimicrobial products. We look forward to working with members and staff of this Subcommittee in the development of a process to speed up the registration program to eliminate unnecessary, and unproductive registration delays.

Expedited Review

The 1988 FIFRA amendments, under Section 3(c)(3)(B) created an "expedited review" for registration applications which are identical, or substantially similar, to a currently registered pesticide product. FIFRA now requires that the applicant receive notification from the Agency as to whether or not the application is complete within 45 days and subsequent to such determination, that these applications be approved or denied within 90 days. This process is not working and thus even simple label changes and applications to register products which are identical to other previously registered products can take over a year to complete. Congress created expedited review and specifically earmarked \$2 million to eliminate registration backlogs in 1988. Yet, five years later, EPA is still not utilizing this tool.

CSMA recommends that the Subcommittee legislatively compel EPA to implement a procedure whereby under FIFRA section (3)(c)(3)(B)(ii)(I), any applicant who does not receive notification within 45 days after EPA's receipt

of an application as to whether or not his application is or is not complete, then such application must be deemed by EPA as complete. Furthermore in the event the applicant does not receive notification as to the acceptance or denial of the application within 90 days after receipt by EPA of the complete application, then pursuant to FIFRA section 3(c)(3)(B)(ii)(II), such application must be deemed by EPA as approved.

Under this suggested procedure which follows the times mandated by Congress under the current law, EPA should be permitted to only refuse to issue an approved application after expiration of 90 days if the Agency, within 15 days, was planning to issue a Notice of Intent to Suspend or Cancel the active ingredient registration for the same uses. The deadlines set forth could not be extended by EPA for reasons having to do with administrative workload. Furthermore, in the event a new registrant wishes to obtain a stamped approved label for use in the states, it could do so by merely having an agent present such label for appropriate stamping at an EPA designated office.

Under this suggested procedure, hundreds of applications for products which are similar or identical to those already registered and on the market would move quickly. Implementation of this procedure would therefore greatly assist in breaking the EPA registration log jam which is precisely what this Subcommittee and Congress directed the EPA to accomplish over five years ago.

FIFRA Fees - Registration and Reregistration

FIFRA was substantially amended in 1988 to provide for the faster "re-registration" of hundreds of pesticide active ingredients. The 1988 FIFRA amendments imposed annual maintenance fees on all pesticide product registrations, and a one-time fee on pesticide active ingredients in order to help pay for the program. The annual maintenance fees were to raise \$14 million per year over nine years, for a total of about \$126 million.

The 1988 amendments set the annual fee at \$425, but EPA could adjust it annually so as to raise \$14 million. The statute also set per company "caps" of \$20,000 for those holding over 50 registrations. EPA adjusted the basic maintenance fee to \$1,300 for 1990 and 1991 but still fell short of collecting \$14 million.

In its budget for fiscal year 1992, after much negotiation between CSMA and other industry groups and EPA, an agreement was reached on a package of FIFRA amendments to:

1. Raise \$14 million by increasing the maintenance fee caps to \$55,000 and \$95,000;
2. Create lower caps for small businesses at \$38,500 and \$66,500;
3. Require additional EPA resources of \$2 million to be dedicated to implementing the expedited review of "me-too" registrations;
4. Require EPA to provide a thorough accounting of revenues and

disbursements from the maintenance fee trust fund.

The Senate and House included the FIFRA fee package in legislation making technical corrections to the 1990 Farm Bill, and the new provisions were signed into law in December 1991.

Despite the fee agreement, EPA early in 1992 informed Congress and industry that the Agency over the next six years will fall short of funds necessary to complete its reregistration activities. EPA, therefore, sought additional fees in its 1993 budget. That fee request was denied, but it is clearly the Agency's intent to again seek new fee authority in its fiscal year 1994 budget.

This Subcommittee and Congress should withhold assessing any additional fees on registrants, or granting any additional fee authority to EPA pending a thorough review of the reregistration and registration programs. Such a review must include an examination of funds collected and utilized in both programs thus far. It is obvious that throwing more money at the Agency isn't going to improve the productivity of this program.

The Subcommittee should be aware that the Agency continually cites the deadlines imposed by Congress in completing the reregistration task as the reason why it has not been able to implement a successful registration program. EPA has shifted personnel from the registration function which affects registrants on a daily basis to assist in the reregistration program for active ingredients and other products which must be completed by 1997. We suggest the Subcommittee examine the deadlines for completion of the reregistration process with an eye toward balancing equities between the

registration and reregistration programs.

The charging of maintenance fees imposes burdensome financial requirements on companies holding registrations since these fees are collected on a per registration basis. These registrants cannot and should not be made to bear more of the financial burden, particularly because the registration program has failed. Before any additional fees are charged, the program must be remedied to permit the registration and hence the marketing of pesticides which are in compliance with EPA requirements.

Guidelines

Current FIFRA language at section 3(c)(2)(A) states that the Administrator shall publish guidelines specifying the kinds of information which will be required to support the registration of a pesticide and shall revise such guidelines from time to time. While the data requirements for obtaining a registration are set forth in 40 CFR Part 158, the actual guidelines themselves have been made available to registrants from the National Technical Information Service (NTIS). However, the manner in which EPA staff uses these guidelines has significantly delayed registrations and needs to be corrected.

Often, in the pursuit of a registration, applicants will visit EPA to discuss data requirements and appropriate provisions and protocols under the existing guidelines as available from NTIS. There is no objection from industry to this procedure but, often times, when the applicant returns with the appropriate data as discussed with the reviewer, the reviewer reaches

into a drawer, pulls out unpublished changes in the guidelines and directs the applicant to conduct additional testing under these unpublished protocols. It is extremely frustrating to registrants who, in good faith, conduct studies only to come back and have the reviewer impose new requirements without proper justification before registrations are granted.

Accordingly, CSMA believes that the guidelines and modifications thereto should be published in the Federal Register. More importantly, the Administrator should provide for public comments in the development, or modification, of such guidelines. Accordingly, it is CSMA's position that an amendment to section 3(c)(2)(A) is necessary to provide for a Federal Register notice to registrants that the Agency, and not the reviewer, through a fair and open process wishes to modify an existing guideline.

Coordination and Synchronization

During the legislative process which resulted in the 1988 FIFRA amendments, CSMA urged the Agriculture Committee to consider a provision which would coordinate and synchronize efforts between the states and the EPA relative to submission of test data and standards of review of such data. Although the provision was not included in the 1988 amendments, CSMA received assurances that the Agriculture Committee would reconsider this matter the next time FIFRA was reauthorized. We are therefore once again bringing this problem to your attention.

The issue of data requirements and uniform standards of review in evaluation of data by EPA and the states continues to be critical for both active ingredient manufacturers and formulators of pesticides in obtaining registrations with EPA and from the various states. The issue initially arose in California under a 1984 law which established a program for the State to fill data gaps. In implementing the law, California adopted its own definition of what constituted a data gap, established a list of studies that it believed needed to be done and created a timetable for filling the alleged data gaps. The State did not incorporate into its program the subsequent adoption by Congress of the 1988 FIFRA amendments which prescribe reregistration timetables and data call-ins to fill many of these same data gaps.

In establishing its own expedited reregistration program to fill data gaps, the State of California put forth its own agenda and time-table which is, from time to time, in conflict with the federal requirements. CSMA recognizes the need to fill data gaps at both the state and federal level and is not suggesting that the state requirements be necessarily preempted by EPA decision-making. However, CSMA does urge that as part of reregistration the states and EPA coordinate and synchronize data requirements so that only one set of data needs to be generated within the same timeframe and that the standards of review used by both EPA and the states for examination and evaluation of new and existing data are the same. The issue has continued to evolve in importance as the states of Arizona and Florida have begun to impose submission of different data requirements under varying time periods.

Unnecessary, repetitive, and redundant testing actually delays the closing of data gaps. Valuable time, energy, and resources, which could be used to develop new data, are wasted in refocusing on gaps that have already been, or are in the process of being filled.

In any FIFRA legislation, Congress should address this important uniformity question and move to eliminate the uncertainties over data gaps on active ingredients once and for all. We believe adoption of legislation (H.R. 3882) introduced by Representative Gunderson in the last Congress, would have accomplished this goal. The Gunderson bill would require that when data is requested by one or more states or federal agencies, the EPA shall coordinate and synchronize such data requests to avoid unnecessary repetition and redundancy. The provision would not preempt the states, Mr. Chairman, but we believe it would foster proper consultation between state and federal regulatory agencies. We expect the introduction of a similar proposal this year and look forward to working with the Subcommittee toward solving this problem.

Reduced Risk Pesticide Policy

In July of 1992, EPA published its proposed Reduced Risk Pesticide Policy which has a very worthy goal of encouraging the development and production of pesticides presenting lower risks than those presently on the market. The problem is that the proposed policy itself would not be needed if the pesticide registration system were working properly. Under the proposal, EPA would attempt to employ economic incentives giving priority in the

registration process to lower risk pesticides and would reassess the registrations of existing pesticides with restrictions or cancellations of products currently on the market. The real concern is that the program would require making judgments as to lower risks based on incomplete data, allowing the public to participate in the establishment of a list of pesticides which allegedly pose higher risks and would permit an indictment like process to remove them. The draft policy would be grossly unfair to waiting applicants or existing registrants.

The policy would evolve similar to the old Rebuttable Presumption Against Registration of 1978 (RPAR) now prohibited by FIFRA Section 3(c)(8) which provides that there can be no interim administrative review without a validated test or other significant evidence. Additionally, the provision violates Section (c)(5) of FIFRA which prohibits EPA from making any lack of essentiality a basis for denying a registration.

As proposed, this Reduced Risk Policy would affect not only active ingredients but registered pesticide products. Thus, the policy would pit active ingredient producers and producers of end-use registered pesticides against each other as they compete for a quicker registration turn around by advising that their active ingredient or pesticide product presents a reduced risk as compared to another product. Instead of promoting and encouraging innovation and the development of new active ingredients, the policy would actually discourage such development.

EPA continues to place heavy emphasis on this proposal and is seeking OMB approval to gather information from active ingredient producers and to issue a Pesticide Regulation Notice advising registrants of methods in which to elevate their active ingredient to achieve priority in the registration process. The policy may result in enormous inequities for a responsible manufacturer who has been waiting in line for his registration only to be passed over by a late arriving active ingredient or pesticide product with allegedly reduced risks. The system as envisioned by EPA is fraught with unfairness and we submit, if implemented, will be the subject of widespread legal challenges.

It makes no sense to us that the Agency continues to emphasize this proposal instead of looking at the registration system and solving its problems. Surely, the easiest way to encourage innovation and development of reduced risk pesticides in a fair and equitable manner, is to untangle the registration system and make decisions in a prompt and orderly manner.

We urge the committee therefore to direct EPA to put its resources into correcting the deficiencies in the registration program instead of taking on new and complicated projects which will result in the diversion of staff which could be working on product registration.

Preemption and Uniformity - Local Jurisdiction

CSMA, along with other members of the Coalition for Sensible Pesticide Policy, support consistent and uniform pesticide regulation by the federal and state government, and preemption of local regulation.

CSMA is pleased that EPA also supports amending FIFRA to limit local regulation in recognition of the burden that conflicting regulation among a potential 83,000 jurisdictions would pose both to its regulatory program and to interstate commerce.

Cancellation and Suspension

Over the past few years, EPA has expressed concern over what it considers to be the cumbersome and time-consuming process required to cancel or suspend a registration. CSMA understands the Agency's concern and believes it must be provided the tools to promptly address pesticides which pose an unreasonable adverse effect to human health or the environment. We also believe that the continued safeguards afforded through administrative adjudicatory hearings are in fact necessary and proper. This process ensures an adequate chance for rebuttal by the registrants as well as a proper forum for consideration of all relevant factors for cancellation or suspension of a pesticide. CSMA will continue to objectively look at any reasonable proposal proffered by EPA and others concerning this issue but remains committed to maintaining appropriate procedural safeguards.

Posting and Prenotification Requirements For Do-It-Yourself Homeowners

In recent years, Congress has been asked to consider the notion of mandatory posting of a warning sign on properties treated by do-it-yourself homeowners as well as the possibility of prenotification of abutting property

owners by homeowners prior to the use of lawn care products. The EPA registration process is founded on scientific information which includes a risk/benefit analysis. By granting a product registration, EPA has concluded that use of the pesticides according to the label precautions and instructions does not impose unreasonable adverse effects to man or the environment. It is CSMA's position that current label precautions are adequate to protect man and the environment and that posting by homeowners is unnecessary.

A number of facts substantiate the position that posting and prenotification requirements should not be mandated for homeowners who apply their own pesticides. These are as follows:

1. The homeowner is in possession of the product label which provides specific instructions on appropriate use areas, target pests, dilution rates, any hazards, practical treatment and proper storage and disposal;
2. Posting and prenotification by homeowners are not practical and are not reasonably enforceable;
3. The scientific data demonstrate that there are no significant risks from exposure to either homeowners or bystanders.

It is CSMA's position that FIFRA provides comprehensive and appropriate regulation for all types of pesticides. The scientific studies required by FIFRA, particularly under the reregistration program, will determine if any additional regulatory measures are necessary. In addition, the states may impose further registration requirements on pesticide

manufacturers prior to permitting sale of specific products. These two regulatory systems (federal and state) make the pesticide industry one of the most highly regulated.

CSMA strongly believes that the Agency should refrain from issuing such guidance as it applies to individual homeowners and instead should spend appropriate resources in determining under the reregistration process whether additional restrictions should be placed on specific active ingredients used in the manufacture of lawn care pesticides.

Delancy Clause

The Ninth Circuit Court of Appeals decision in Les V. Reilly 968 F.2d 985 (Ninth Cir. 1992) has reemphasized the need for Congress to enact a "negligible risk" standard for establishing legal pesticide residues in food. A zero-risk standard, as required by the Les decision, would significantly limit the availability of pesticidal products which offer substantial benefits to society without threatening the public health.

Overly restrictive definitions of "negligible risk," as proposed by Representative Waxman (D-Cal)(H.R. 872) are equally troublesome. CSMA supports a "negligible risk" standard consistent with present risk ranges (1×10^{-5} to 1×10^{-6}) used by EPA, FDA and other Federal agencies. The risk assessment process used by EPA in setting tolerances should not be prescribed in statute, as is done in H.R. 872; it should instead provide EPA with appropriate scientific flexibility and discretion.

Certification and Training

In past FIFRA hearings, there has been some discussion concerning certification and training requirements and whether these should be extended to persons using general use pesticides. Some interests have advocated that commercial application of any pesticide should be made subject to certification and training standards even if the pesticide is applied incidental to employment.

Implementation of such a policy would be folly and would require certification and special training for persons such as:

A busboy in a restaurant who wipes table tops with a disinfectant cleaner;

A school custodian who cleans the rest rooms with a tile and bowl cleaner;

A building superintendent who eradicates a hornets nest with general use wasp and hornet spray;

A nurse or doctor using a hospital disinfectant;

Or even a housekeeper who freshens up a room with a disinfectant spray.

In each of these instances, the pesticide applied is a general use product under section 3 of FIFRA, registered as such because EPA has reviewed it and determined that it will not cause unreasonable adverse effects to man or the environment. Such factors as low toxicity when compared to other pesticides that may be classified as restricted use, are already taken into account. EPA also approves the label and specific

directions for use.

Consumers of general use pesticides can be expected to use the products safely in accordance with direction without costly and burdensome training and certification. It's not necessary or appropriate to burden the public with such requirements, limiting an individual's ability to quickly, easily and inexpensively solve pest problems affecting public health and safety.

We believe that certification and training requirements are appropriate for "commercial applicators" who apply pesticides as the principal part of their business and we believe any legislation concerning such certification and training should reflect this distinction.

Conclusion

CSMA member firms are deeply concerned and frustrated with the EPA pesticide registration process. We submit that the Subcommittee should compel EPA to properly perform this function before the Agency assumes new responsibilities with the respect to the regulation of pesticides. We specifically, as indicated herein, object to implementation of a Reduced Risk Pesticide system and other initiatives which divert resources resulting in even further delay of the registration process.

In the past, this Subcommittee has been reluctant to legislate a regulatory program. The industry has accepted this decision over the years hoping that the program would be rectified. However, that has not happened and now this Subcommittee must take the responsibility for seeing to it that its many deficiencies are corrected.

I want to thank you Mr. Chairman, and the Ranking Minority Member, Mr. Roberts together with the rest of the Committee for recognizing the serious shortfalls of the registration process by holding these hearings. As always, CSMA stands ready to work with the Subcommittee and with the Agency to rectify these problems.

STATEMENT OF
WILLIAM GULLICKSON
CHAIRMAN, CHEMICAL PRODUCERS AND DISTRIBUTORS ASSOCIATION

BEFORE THE

SUBCOMMITTEE ON DEPARTMENT OPERATIONS,
AND NUTRITION,
COMMITTEE ON AGRICULTURE

UNITED STATES HOUSE OF REPRESENTATIVES

JUNE 8, 1993

I am Hunter Hanshaw, Manager of Regulatory Affairs for the Chemical Producers and Distributors Association (CPDA), and I am accompanied by William D. Gullickson, Jr., President of McLaughlin Gormley King Co. (MGK) in Minneapolis, Minnesota and Chairman of CPDA's Board of Directors. I appear before members of the House Subcommittee on Department Operations, and Distribution to discuss a number of pesticides issues of importance to our association.

By way of introduction, the Chemical Producers and Distributors Association is a voluntary, non-profit membership association consisting of about 100 member companies engaged in the manufacture, formulation, distribution and sale of some \$4.0 billion worth of products used on food, feed and fiber crops, and for lawn, garden and turf care.

Today, I would like to share my thoughts with members of the subcommittee on several specific issues relating to the Delaney Clause, to EPA's registration and reregistration programs, as well as questions surrounding reregistration fees and minor use. I will first discuss the Delaney Clause and its impact on food safety.

DELANEY CLAUSE

The U.S. Court of Appeals for the Ninth Circuit ruled in Les v Reilly on July 8, 1993 that Section 409 of the Federal Food, Drug, and Cosmetic Act, the "Delaney Clause", requires EPA to apply a "zero-risk" standard for carcinogens when setting permissible tolerances for pesticides in processed food.

The Les ruling could have a disastrous effect on the abundance and safety of our nation's food supply and the agricultural industry as a whole. The decision could lead to the cancellation of thirty five different pesticides, which comprise more than 10 percent of the basic pesticide ingredients used in agriculture, and hundreds of different uses which were previously approved by EPA.

In 1958 Congress passed the Delaney Clause, which states in part that "no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal." EPA had previously construed this clause using a de minimis standard for pesticide residues in processed food.

Under the de minimis standard a tolerance was granted if the human dietary risk from a pesticide was so remote that the threat of contracting cancer was "at most negligible." The Ninth Circuit, however, has interpreted the Delaney language "found to induce cancer" to mean no traces of carcinogens in residues for processed food, regardless of how borderline the response in test animals or how marginal the risk may be to consumers.

The "zero risk" standard is simply unworkable for establishing reasonable risk evaluation. When Delaney was promulgated, almost thirty five years ago, the usual scientific testing standards measured in the parts per million. Scientific detection standards now measure in the parts per trillion and greater, resulting in the detection of carcinogens which present at the most a remote and negligible threat to the public.

A mass revocation of these pesticides will likely lead to fruit, grain, and vegetable price increases and a decline in the quality of our food. A subsequent reduction in the consumption of these products by our citizens could lead to the erosion of our health and the nutritional integrity of our diets. The American Cancer Society strongly maintains that Americans need to double their present consumption of fruits, vegetables, and fiber to reduce the incidence of various types of cancers. Implementation of a "zero-risk" Delaney clause would therefore likely increase the incidence of cancer across the country.

The EPA has a vast wealth of resources, personnel, and scientific knowledge it uses to draft pesticide policy. As a federal agency it has the regulatory discretion to interpret statutes in order to effectuate this policy. EPA has long determined that a "negligible risk" standard most effectively protects the health of the American consumer and maintains the abundance of our nation's food supply.

To avoid the unnecessary cancellation of numerous valuable pesticides Section 409 of the FFDCA should be amended to reinstate the flexible concept of "negligible risk" when setting permissible tolerances for pesticides in processed food.

We at CDPA strongly support H.R. 1627, the Food Quality Protection Act of 1993. The bill would create a single negligible risk standard for tolerances for pesticide residues in raw commodities and processed food. EPA would be responsible for defining negligible risk in light of evolving science, taking into account different routes of exposure to a pesticide and sensitivities of population subgroups. EPA would be required, where reliable data are available, to calculate the dietary risk posed to food consumers by a pesticide on the basis of the percent of food actually treated with the pesticide and the actual residue levels of the pesticide that occur in food.

Again we commend this bill to your attention, and respectfully urge that it be included as part of a FIFRA markup.

EPA PESTICIDE REGISTRATION AND REREGISTRATION PROGRAMS

While the Agency has expressed considerable concern and expended much energy about the necessary funding of its programs, it has not spent a commensurate effort at implementing the 1988 FIFRA "Lite" programs. Though the Agency has collected millions in fees, it has not fully implemented its regulatory program in a timely manner. We at CPDA would like to take a moment to discuss: 1) Fast Track; and, 2) Label Changes, and 3) the Funding of the Registration and Reregistration programs.

Fast Track

For almost five years, the EPA has been implementing the provisions of the 1988 FIFRA "Lite" amendments, but has not been able to clear the backlogs that exist in the registration division. This backlog especially impacts "fast track" or "expedited review" products, despite Congressional authorization for up to \$2 million per year of reregistration maintenance fees to be used to implement fast track.

During the 1988 legislative debate over the FIFRA amendments, we at CPDA strongly supported the provisions for an expedited review of "me-too" products and label changes. As formulators and distributors of generic end-use products, this expedited review provision was the most important aspect of the registration process to our segment of the pesticide industry.

We have been disappointed by the failure of the Agency to fully implement the "expedited review" process. On the front-end review process, the Agency has done an adequate job of reviewing the original documents and determining if they are in order and complete. This initial review has usually been completed in forty-five days. The second phase -- requiring ninety days -- provides for the finalization and approval or rejection of an "expedited review" application. It appears that "an expedited review" product gets no special handling in this second phase. It seems simply to go to the bottom of the pile. We believe EPA should utilize a two stack approach -- one stack for "expedited review" and another for all other products; with appropriate EPA personnel assigned to each.

The so-called ninety day second phase has taken anywhere from six to eighteen months, with some isolated examples that required more than two years. One small company has waited more than three years for an amendment to a "me-too" label, but during this time has had to amend its label three more times and still has not gotten the product registered.

The Agency has not moved quickly enough to solve these "fast track" problems. Some simple label changes, such as alternative

brand names or the addition of alternate sources of supply to a confidential statement of formula, that take fifteen minutes to review, instead, take six months to filter through the process. Many label changes need only prompt responses, without delegation of responsibility. We see little evidence that the Agency has moved quickly enough to put the appropriate personnel in place to handle this workload. The Agency has not effectively spent the funds nor spent a proportional share of the maintenance fees to address this pressing problem. We have no accounting on how the EPA spent \$2 million in FY92 on fast track.

We at CPDA would like to offer some suggestions on how to correct some of the problems associated with the expedited review situation.

First, we believe that the resources within the expedited review program should be used to hire or assign an expedited review person for each of the eleven project managers, so that the applications can be reviewed in a timely manner.

Second, although expedited review applications are "coded," we recommend that the applications for fast track should be color-coded so that they can be easily recognized by EPA officials.

Third, if the Agency misses the 90-day deadline for completing the review, then it should give the registrant an update every thirty days until the pesticide is registered.

Fourth, CPDA would like to see a notification system set up for identical me-too products, patterned after notification section 5 of TSCA. Under the rule, if EPA does not respond within 90 days, the me-too product can be marketed. The proposed language could read similar to the TSCA provision.

Label changes not requiring a scientific review, such as a simple revision to wordings of a precautionary use statement, should also fall under the notification process.

CPDA believes EPA should provide the registrant written confirmation upon receipt of a registrant's notification. A registrant could provide a self-addressed, stamped post card which could be mailed to the registrant upon receipt of the notification. This will help the registrant when it deals with state registration officials, (i.e California), which require written confirmation of registration.

Fifth, as an alternative approach to the above mentioned notification plan, the administrator could establish a standard for me-too products and label changes, and establish specific regulatory procedures for the registration of these products. A rule could:

- (A) identify all substantive and procedural requirements which must be met in order to market a me too product or make a label change.
- (B) create record keeping for documents demonstrating compliance with these requirements; and
- (C) create a mechanism for assigning to each such product an individual identifying registration number for record keeping and reporting purposes.

A substantially similar or identical product could be deemed to have been registered upon notification by the registrant to EPA by registered mail of the name of the product and certification by the registrant that the requirements of this subsection have been met. A stamped approval label must be returned to the registrant within 30 days of such notification.

Sixth, it is important to reduce the amount of redundant and unnecessary testing for "me-too" products, and reduce the amount of acute toxicity testing by batching the available test data for substantially similar products.

Seventh, we recommend that the "out year" of the program -- FY95, FY96 and FY97 -- be required to allocate a full \$2 million per year toward expedited review, something they were directed to do in 1988 but have apparently never done.

Label Changes

Several different offices and programs within the EPA's Office of Pesticide Programs (OPP) require, at different times, changes on a pesticide product's label. Some of these EPA mandated changes might be to change an ingredient, an inert, or a use. Sometimes a label might need to reflect some new set of directions or warnings about use or specific health and safety instructions. Sometimes the Agency may require that the registrant reshape the label or reduce its size, or place new instructions for proper disposal of the container on the label.

Specific programs also address specific needs to change the label, such as the Endangered Species Program, container rinsing proposals from the new FIFRA "Lite" requirements, and other programs. The Label Improvement Program (LIP) also seeks to update the label and make appropriate changes. In addition, label changes may be requested from the Air and Water Divisions of EPA to conform with the Clean Air and Water Acts. Many different offices and programs require the registrant to make changes on label, but no one part of the Agency coordinates appropriate label changes. These various programs do not know what the other parts of the Agency are doing about label changes.

A company frequently makes a label change in response to an EPA office's request, and prints thousands of new labels, only to find that another EPA office, program, or division is requiring additional changes. Many companies print up new labels just in time to throw them in the trash. It can be an expensive, time-consuming and frustrating experience and means money and jobs for many small businesses who are fighting to compete in a tough market.

To give you some idea of the magnitude of this problem, a random sampling of CPDA companies indicates that, on average, they spent in excess of \$808,600 over the past 6 years on labels which were ultimately discarded. For these companies, this translated to approximately 5,600 wasted man-hours and represented more than 1,613,000 labels which never saw the light of day. When one extrapolates these figures to the entire industry, it becomes very apparent that a problem exists which needs to be addressed quickly.

A number of CPDA member companies cite a definite lack of coordination between product managers, Label Improvement Program (LIP) personnel and other Agency staff in formulating label requirements. Representatives of one CPDA member company, for example, report that they have been required to write the Confidential Statement of Formula (CSF) for the same pesticide in different ways for different EPA personnel. This same company also notes that it has received conflicting instructions from various Agency personnel regarding the wording of the Precautionary Statements found on phenoxy labeling.

Other OPP programs which affect reregistration, the container disposal program, the regulation of inerts, farm worker protection standards, certification and training requirements, and product reclassification will certainly have an impact on the fate of present labels or the re-labeling of existing stocks.

One small-sized formulator of lawn and garden products responds that it seeks to reduce waste in its labeling operations by printing small quantities of labels on a more frequent basis. However, the company also notes that it is then faced with the disadvantage of having to pay a significantly higher unit cost per label. In these troubled economic times, a small business cannot afford to incur such needless and unnecessary costs.

In an effort to improve the way in which the Agency handles label revisions, we at CPDA offer the following suggestions which we feel will consolidate and better time EPA's labeling regulatory activities.

First, one office in OPP, within the Registration Department, should coordinate all label changes from all programs, all product managers, and all divisions so that there is no confusion about the necessary changes needed to comply with EPA's mandates. At

present, many different offices and programs require the registrant to make changes on the label, but no one part of the Agency coordinates appropriate label changes.

The Agency has made considerable strides in coordinating this effort, however problems still exist. For example, in EPA's negotiations with the 2,4-D Task Force it agreed that existing 2,4-D labels would be used until June 15, 1994, after which a label change would be required. However, for these same products EPA's mandated label change date for PR Notice 93-3 wetlands language, PR Notice 93-6 heightened efficacy language and PR Notice 93-7 Worker Protection standards language is April 24, 1994. The Agency coordinated the dates for the three PR Notices, however it neglected to determine what other label changes were being implemented and at what date. The oversight will essentially result in the shortening of the 2,4-D deadline a month and a half from June 15, 1994 to April 24, 1994.

Second, one date each year should be selected for all EPA-mandated label changes. We suggest October 1st as a good date because it represents the end of the growing season as well as the beginning of the new fiscal year. All label changes could be effective on this date, so that companies can start production in the fourth quarter for the following Spring's use.

Third, companies need enough lead time to implement the Agency's requirements for both new product labeling and for the re-labeling of existing stocks. We propose that the Agency provide companies with at least a year's notice to adopt EPA-mandated label changes.

Of course, CPDA understands that there will be cases involving an imminent hazard or some other emergency situation where an immediate change on product labeling is merited. In those instances, we believe that the Administrator of EPA should be given adequate flexibility to implement the necessary labeling requirements outside of the time schedule set forth in CPDA's recommendations above.

CPDA believes that this labeling proposal, if adopted, will not only save industry time and money, but will eliminate duplication of effort within the Agency and enable EPA to channel its valuable technical resources into other beneficial program areas.

We applaud this subcommittee's effort last May 17th when it included this label proposal in the "en bloc amendment" provision to HR 3742. We strongly urge your inclusion of this amendment in any FIFRA bill that is reported in the 103rd Congress.

REREGISTRATION COSTS

In the Fall of 1988, the Congress worked out a compromise to fund the cost of the reregistration program. This compromise included: 1) a \$150,000 fee per active ingredient, with the goal of raising about \$32 million; 2) a maintenance fee designed to raise \$14 million per year for nine years, based on a fee per product; and, 3) no registration fees during the nine year reregistration period.

Although this program was adopted in 1988, CPDA member companies suffered important economic consequences. The maintenance fee system imposes a per product fee, regardless of sales volume, and therefore, has a disproportionately adverse economic impact on formulators, distributors, and companies that sell large numbers of end-use products, all of which are low profit margin products. A flat fee system actually operates as a regressive tax because the fees paid by small companies represent a substantially higher percentage of their total sales and profits than they do for larger companies. Consequently, the present system seriously disrupts the competitive balance between large and small firms.

Many small formulators and distributors produce products for a special local or regional market, or for minor crops. They are produced and sold in low volume quantities. Some products only generate annual sales in the thousands of dollars. Over the last three years, we have witnessed a significant drop of minor use pesticide products, due in great part to the maintenance fee program.

While small formulators and distributors continue to struggle with an unfair system that places a significant portion of the reregistration burden on them, the Bush Administration, in its 1992 annual budget, suggested the lifting of the caps on the existing maintenance fee program. The goal of the maintenance fee program is to raise \$14 million per year, a goal that was not attained in 1989-1991. In 1991, the program raised about \$11.0 million, compared to \$11.5 million the year before. We strongly support the goal of raising \$14 million, but strongly oppose removing the caps to achieve this goal.

The original maintenance fee program (1989) established a \$425 fee for its first 50 products, and \$100 per product for those numbered 51 to 200. The maintenance fee system was then revised in 1990 so as to establish a fee of \$650 for the first product, and \$1,300 for each product thereafter, regardless of the sales volume or profitability of products. For the first 50 products, a cap was set at \$20,000. Consequently, a producer would have paid \$650 for his or her first product, and then \$1,300 for the next 14 products, plus a portion of the 15th product. Therefore, registrants would pay for their first sixteen products (or portion thereof), and then

products 17 through 50 would fall under the \$20,000 cap.

For products 51 through 200, there was a fee of \$1,300 per product until one reached a total cap of \$35,000. The cap was reached by the time a company reached a 62nd product. Products above 63 fell under the \$35,000 cap.

If the caps had been removed, we could have seen up to 6,000 to 7,000 products deleted (perhaps as many as a total of 17,000 products, or about 34% of the number of registrations in 1988), a drop of about 30 percent of products registered in 1991. We do not believe a dropping of the cap represents good public policy due to its adverse economic impact on the pesticide industry, production agriculture, and minor use crops.

There is no correlation between the size of the company and the number of registrations. Many small companies have large numbers of end-use product registrations. Deleting the cap only further exacerbates the inequities that already exist in an unfair system which forces small formulators and distributors to pay a disproportionate share of the maintenance fee system and the costs of reregistration.

Although we firmly believe that the total removal of the caps would create economic hardship and have a disproportionate impact on small businesses, sellers of low volume, low profit, minor use products, and formulators and distributors who held large numbers of products (but not necessarily large sales), we at CPDA joined with the National Agricultural Chemical Association (NACA), the Chemical Manufacturers Association (CMA), the Chemical Specialties Manufacturers Association (CSMA), and the International Sanitary Supply Association (ISSA), and EPA to seek a solution to this problem.

In October of 1991, we reached agreement on a package of amendments that the House and Senate adopted as part of the Farm Bill corrections package and was signed into law by President Bush. It included provisions which:

- o adjust the cap for the first 50 products from \$20,000 to \$55,000, and increase the cap for products 51 or more to \$95,000;
- o maintain the fee at \$650 for the first product, and \$1,300 for each additional product up to the adjusted caps;
- o establish a small business cap at \$38,500 for the first 50 products, and \$66,500 for products 51 or more. A small business registrant is a corporation, partnership, or unincorporated business that has 1560 or fewer

employees and during the last 3-year period had an average annual gross revenue from chemical sales that did not exceed \$ 40,000,000 [See FIFRA Section 4(i)(4)(C)(iii)];

- o beginning in 1992 and continuing through 1997, adjust the payment timetable from March 1 to January 15, thus allowing the Agency to collect funds earlier to mitigate its existing cash flow problems;
- o allocate one-seventh (1/7) of the maintenance fees collected by EPA in 1992, 1993 and 1994, and in 1995, 1996 and 1997 up to \$2 million annually to accelerate reregistration (Fast Track) and expedited processing of funds.

This amendment package raised \$15.1 million thus fulfilling its statutory requirements included in the 1988 FIFRA amendments. In fact, it created a surplus of at least \$1,100,000.

We at CPDA therefore, remain committed to fulfilling the compromise that was created in 1988, with a pledge to help raise \$14 million per year for the maintenance fee program, with a commitment not to implement a registration fee system during the duration of the reregistration program, and with an understanding that the industry could collectively raise about \$146 million (\$32 million in active ingredient fees and \$114 million in maintenance fees) to assist, in part, to pay for the costs of the reregistration program.

REREGISTRATION RECASTING

During the last three years, EPA has recalculated the cost of the reregistration program, and each year has substantially redone its estimate. From a \$160,000,000 figure to now less than \$20,000,000 the Agency has consistently revised these numbers downward.

When the new figures are released this Spring (1993), it will be especially important to obtain a clear and detailed accounting of where and how the monies have been spent during the initial four years of the program. In essence, before we think about a \$20 million increase in the program should we not carefully review the present program to identify where cost savings can be achieved and efficiencies could be implemented? How can EPA streamline its programs to eliminate duplication and waste in the reregistration program?

Pursuant to Section 4(K)(S) of FIFRA, the EPA should provide a detailed annual accounting of all funds collected or disbursed.

These detailed reports should be made available to the public. As per the letter of October 17, 1991, to Senators Patrick Leahy and Richard Lugar, and Congressmen E. Kika de la Garza and E. Thomas Coleman, and a separate EPA letter, there was a general understanding that we would collectively determine the sufficient level of "detail" needed to describe this process. Perhaps soon we will have a comprehensive detailed cost accounting of the reregistration programs, and therefore, be in a much better position to determine what, if any, increases are needed in the program.

It is also our understanding that the 1988 FIFRA amendments require that the maintenance fees be utilized to support activities within the Office of Pesticide Programs (OPP) and its activities associated with the nine year program to reregister pesticides and the expedited registration of "me-too" products and label changes. Our understanding is that maintenance fees may not be used for other on-going projects within OPP or within other offices of EPA. The previously cited letter also addresses this problem and asks the agency for a full accounting of the program. When we obtain complete and detailed responses to these questions, only then can we come up with an accurate cost of the reregistration program and a definite assessment of the shortfall.

If a shortfall does exist, we need to fully explore all options for raising the funds needed to fund the reregistration program. We at CPDA believe that two possible options are to seek an increase in general appropriations for EPA under the budget agreement, or find the necessary funds within the existing EPA budget.

Industry has collectively accepted the need to raise \$146 million (our understanding of the 1988 FIFRA amendments), and has recently tripled the maintenance fee caps so that we can fully raise the \$14 million per year. In addition, we will spend more than \$3 billion in testing old products as part of the reregistration process -- a nine year process we believe will instill increased public confidence in the EPA's pesticide program.

We pledge our best efforts to work with the Congress and to identify and correct this problem.

REGISTRATION FEES

In President Bush's Budget request for FY '93, the previous Administration included a request for \$15 million in registration fees to help fund the EPA pesticide program.

We at CPDA strongly oppose an effort to raise another \$15 million per year from an industry which just recently (October-November 1991) agreed to nearly a three-fold increase in maintenance fees.

We urged the Congress to reject such future request for additional fees, and to support current Section 4(i)(6) of FIFRA, as added by the 1988 amendments, which, in part, concluded:

"During the period beginning on the date of enactment of this section [October 25, 1988] and ending on September 30, 1997, the Administrator may not levy any other fees for the registration of a pesticide under this Act..."

We clearly appreciated the Congress' willingness to delete the Gam amendment which would have imposed a \$10 million registration fee from the 1993 appropriation bill. Especially we applaud the bipartisan efforts of Chairman E. (Kika) de la Garza and Ranking Republican Congressman E. Thomas Coleman (R, MO) in defeating this proposal.

Two years earlier, in October of 1990, President Bush's budget included a specific pesticide registration fee designed to raise \$14 million per year or \$70 million over five years. With the support of this subcommittee, the House and Senate Committees on Agriculture, and the leadership of Chairman E. (Kika) de la Garza, this proposal was deleted from the President's FY '91 budget reconciliation package.

We greatly appreciate your concern and your interest in this important issue and respectfully request that any similar initiative in the 103rd Congress be defeated.

Clearly, the jurisdiction for FIFRA and EPA registration fees belongs to the House Agriculture Committee and the Senate Committee on Agriculture, Nutrition and Forestry, and should continue to remain there.

We believe that a huge increase in registration fees will add new costs to pesticides, will discourage research and development, delay the introduction of new, cleaner and more effective labels, reduce jobs in the industry, and severely impact small to medium-sized businesses that often sell low-volume, minor use products.

We at CPDA would like to offer the following conclusions:

1. Pesticide registrations are in the public interest. Pesticides allow us to enjoy the safest and most abundant food supply in the world, they protect the public health from disease vectors, and they keep our schools, homes and businesses free from pests. Therefore, there should be no registration fees.
2. Registration fees paid to the U.S. Treasury will not aid the EPA pesticide programs.

3. Registration fees will have an adverse economic impact on our industry, especially small business.

Fees and the Public Interest

For many decades there have been special kinds of user fees for individuals, organizations or companies that have sought special benefits for an indefinable recipient. Visitors to national parks have paid an entrance fee to help defray the cost of upkeep of the park and its facilities. Boaters have paid fees for use of canals and inland waterways. Farmers and cattlemen have paid user fees for allowing livestock to graze on public lands throughout the West. Each of these individuals, organizations or companies has derived a specific level of benefits by utilizing government facilities.

There are, however, three statutes that require pre-clearance of a specific commercial product -- the Federal Food, Drug and Cosmetic Act, the Federal Insecticide, Fungicide and Rodenticide Act, and the Toxic Substances Control Act -- prior to manufacture, sale and distribution of these products. In each case, the federal government acts as clearinghouse, collecting and evaluating scientific data, and ultimately registering pesticides and drugs for public use. In each case, the registration and pre-clearance of products broadly benefits the general public. Since these new products and new uses clearly provide a public benefit, enhancing our quality of life, stimulating new food production, and protecting public health, there should not be user fees assessed on the registration of pesticides.

Pesticides should not be singled out for the special user fees when other pre-clearance statutes, such as those for drugs and animal health products, do not contain any provisions for user fees or registration fees.

Any system of registration fees would, in effect, result in taxing a few to finance a regulatory system that benefits many. Under current law, government fees are authorized only when specific services of some value are rendered to special beneficiaries (31 U.S.C. Section 483a). When government services benefit society generally, the expense of those services should be borne by the taxpayer at large, not by individuals.

The EPA registration process benefits the general public and the American taxpayer, not just those who produce products to be registered. For these reasons, registration costs should be paid with public funds and not special registration fees.

FEES WOULD NOT HELP EPA

The purpose of a registration fee system, one would guess, would be to help pay for, in part, the costs of administering the pesticide registration program. In essence, the fees derived should help the Agency in implementing its program.

The Bush budget proposals of 1990 and 1992, however, clearly stated that the registration fee system would raise funds for the U.S. Treasury, not EPA's budget or the pesticide registration program. As miscellaneous receipts, these funds could be applied to any governmental program or used to pay the national debt. These funds would not enhance the Agency's ability to register pesticides.

Under the Federal Food, Drug and Cosmetic Act (FFDCA), the Agency is authorized to collect fees for tolerance petitions, and these funds are placed in a revolving account that is designed to help defray the costs of the program. The registration fee proposal, however, will not accomplish a similar goal.

Since the monies collected under the IOAA authority will go directly into the U.S. Treasury, not into EPA's registration program, the entire purpose of the program is undermined. Such a program is unreasonable, inadvisable and unworkable.

FEES IMPACT SMALL BUSINESS

This segment of the industry holds numerous pesticide registrations and is largely populated by small pesticide formulators who have their own registrations or who are subregistrants. Many of these formulators produce low-volume, low profit products that could not withstand substantial registration fees. Many of these products are applied on minor use crops and are, therefore, sold in small volumes at low profit. In addition, many of these companies manufacture products for regional sales and distribution, and provide a unique service for regional crops.

In the November 26, 1986 Federal Register, EPA proposed regulations for the imposition of fees for a number of registration activities conducted pursuant to the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). The proposed regulations would have assessed a fee of: \$163,000 for new chemical registrations; \$3,500 for old chemical registrations (i.e., registrations for new products containing pesticide active ingredients which are substantially similar or identical to those currently registered); \$29,900 for new registrations entailing a major change in the use pattern; \$56,600 for new biochemical, biotechnical and microbial registrations; \$4,000 for experimental use permits; and \$5,300 for a food additive.

If the EPA adopted a similar registration fee proposal in 1993, small pesticide producers would be significantly adversely affected. Most small producers hold multiple registrations and numerous labels. Any proposal that arbitrarily establishes a fee based on the number of labels, rather than volume sold, disproportionately affects small formulators.

When these registration fees are combined with other fees, such as those required for tolerances and for registrations required at the state level, as well as potential reregistration fees presently being considered by Congress, the cumulative effect is devastating for small businesses.

Some companies hold U.S. pesticide labels because they are necessary to market certain products internationally. Many Central and South American countries will not issue a pesticide registration for internal use unless it has been registered by EPA. By the imposition of American registration fees, we could lose several international markets for U.S. produced products. Although these sales are frequently inconsistent and result in marginal profits, the imposition of any fees on these products would result in their cancellation, thus reducing potential exports of these formulated products.

Frequently, pesticide producers will initiate contact with the Agency to register a new use or amend a label. On other occasions, the Agency will request that the registrants amend their label or comply with a new registration standard or change a product classification to "restricted use." It has become common for EPA to require labeling changes or amendments on many products on an annual basis to address such issues as farm worker safety, ground water protection, storage and disposal. The pesticide industry is currently incurring tremendous costs from these required products by having to submit amended labels, prepare new product artwork, destroy obsolete label inventories or order small, uneconomical label quantities and, in some cases, re-label existing stock. Under these circumstances, the Agency should not require a fee for changes initiated by EPA to comply with other new standards or regulations.

Many other products are sold on a marginal basis, with low volume sales basically covering the cost of production, marketing expenses, and state registration fees. This type of pesticide provides a basic service to potential customers and provides a business entry for the registrant. Many of these products might be used for minor use crops. With these types of registrations, companies are likely to drop the registration if the Agency decides to implement a registration fee system.

In summary, we believe that any system of registration fees for pesticide registration would have a significant adverse economic impact on the pesticide producers and formulators,

especially small businesses, that manufacture and distribute agricultural pesticides and pest control for lawns and gardens.

PUBLIC HEALTH PESTICIDES

CPDA would now like to share some thoughts on a very important class of pesticides -- specifically, minor use pesticides utilized in public health programs to control and eradicate the spread of disease - carrying insects and pests which threaten our health and well-being.

CPDA strongly supports H.R. 1867, the "Public Health Pesticides Protection Act of 1993" introduced in this 103rd Congress by Representatives Calvin Dooley (D-CA) and Wally Herger (R-CA). The legislation ensures that EPA establish guidelines that take into consideration the need for and benefits of public health pesticides used to combat disease-carrying insects and pests and to ensure that these products are not lost in the reregistration process due to economic reasons alone.

The Dooley-Herger bill contains provisions which would:

- o Define public health pesticide uses in the context of minor uses;
- o Create a separate class of pesticide registration for public health pesticides with a risk-benefit balance, which is separate from that utilized for agricultural pesticides;
- o Require that the EPA Administrator take into consideration "the differences in concept and usage" between agricultural, non-agricultural, and public health pesticides;
- o Require consultation by the EPA Administrator with the Secretary of Health and Human Services on pesticides for public health uses, similar to the existing consultation between EPA and USDA; and,
- o Expedite the registration of products necessary for the protection of public health.

On April 23, 1991, Dr. William Hazeltine, Manager-Environmentalist of the Butte County Mosquito Abatement District in California, appeared before members of the House Subcommittee on Department Operation's Research and Foreign Agriculture. During his testimony, he eloquently drew attention to the need to create a public health provision in FIFRA, with an emphasis on controlling diseases transmitted by mosquitoes and other vectors.

Many CPDA companies manufacture, formulate and distribute insecticides and rodenticides that attack mosquitoes, flies, ticks,

mites, fleas and other insects, rats and other rodents, and that promote public health. Many of these companies, therefore, emphasize non-agricultural pesticide production and public health issues. Because we share Dr. Hazeltine's concern about public health issues, we at CPDA believe that the public health pesticide provisions of HR 1867 should be adopted as an amendment of FIFRA.

In summary, the Dooley-Herger bill recognizes the unique benefits of low volume minor use pesticide products which are widely used in public health programs to combat a host of insects and pests which transmit harmful diseases to man. It is critical that a wide variety of product choices be made available in order to maintain good mosquito and other vector control programs. Without proper public health programs, vector borne diseases such as malaria and yellow fever might once again become epidemic in the United States. The Dooley-Herger bill will help ensure that this never happens.

PREEMPTION

We at CPDA would like to express our support for legislation which would preempt local jurisdictions from enacting their own rules governing the sale and use of pesticide products. We believe that such regulatory authority over pesticides should be limited to a partnership between Federal and State governments which have the appropriate mechanisms in place to promulgate uniform, sensible regulation based on sound science.

On June 21, 1991, the Supreme Court issued its decision in the case of Wisconsin Public Intervenor v. Mortier. In its opinion written by Justice White, the Supreme Court ruled that local jurisdictions are not preempted by FIFRA from enacting their own pesticide ordinances. In essence, the Court's decision threatens to undermine the existing Federal-State partnership of pesticide regulation by opening up the field of regulation of these products to more than 80,000 units of local government.

At its May 1992 FIFRA markup of H.R. 3742 (the Rose bill) during the 102nd Congress, the DORFA Subcommittee adopted an amendment which preempted local municipalities from regulating the sale or use of pesticides.

This year, Representatives Harold Volkmer and Robert F. Smith are expected to introduce similar legislation. We at CPDA commend Representatives Volkmer and Smith for their leadership on the preemption issue during the 103rd congress. We remain committed in our support of legislation which would amend FIFRA to prohibit the local regulation of pesticides.

MINOR USE

CPDA supports the concept of the Minor Crop Pesticides Act of 1993, H.R. 967. The retention of minor use pesticides used on low volume commodities should remain a key focus of Congress in the reauthorization of FIFRA. Minor crops grown in the United States constitute an industry with estimated sales of \$ 35 billion at the farmgate. These include hundreds of different crops ranging from daily foods (fruits, vegetables, and nuts) to a variety of specialty items (flowers, hops, herbs, trees, shrubs and turf).

As you know, under the 1988 amendments to FIFRA, the U.S. Environmental Protection Agency was charged with reviewing some 600 agricultural chemical active ingredients as part of its nine-year accelerated reregistration program targeted for completion in 1997.

Since its inception, we have witnessed a dramatic reduction in the number of minor use pesticide registrations. To date, 34% of the products originally registered have been dropped. The majority of these product registrations have been held by small companies. The financial burden of maintenance and reregistration fees in combination with the enormous costs of generating the necessary data to support the continued registrations of these chemicals have contributed to their decline. Today, a number of crucial products remain at risk of disappearing from the marketplace.

EPA's accelerated reregistration program has subjected registrants to a number of data submission requirements in defending pesticide registrations for use on minor crops. The costs associated with fulfilling these requirements is formidable when one considers that for each active ingredient, there may be a number of different product formulations used on a wide variety of crops.

The members of CPDA see H.R. 967 as a step in the right direction to ensure cost-effective chemicals remain available for use on low volume commodities. H.R. 967 supplies the flexibility to EPA in addressing minor use registrations. Time extensions, waivers, use of surrogate data, and the creation of a fast track process for these registrations provides the mechanisms needed to support the continued uses of these valuable chemicals. At the same time, the bill conditions these allowances on the certainty that there will be no unreasonable adverse effects on man or the environment.

Moreover, the measure adopts a very broad definition of minor use, encompassing uses of a pesticide on animals, commercial agricultural crops and public health pesticides. A determination of minor use activity is based on economic incentives, rather than on specific acreage requirements, a threshold found in previous minor use bills. As such, current EPA policy is ratified.

Furthermore, we support the creation of minor use programs in both EPA and USDA. Programs of these sort will help in coordinating

policies, consulting with growers and tracking and expediting minor use registrations.

MINOR USE AND DATA COMPENSATION ISSUES

We believe the mechanisms found in H.R. 967, such as extensions, certain waivers and use of surrogate data, in conjunction with the present data compensation provisions found in FIFRA provide ample incentive for pesticide registrants to support these chemicals through the reregistration process and in developing new active ingredients.

While we support the major provisions of H.R. 967, we are opposed to patent term restoration. We believe the extension of patent term periods or the extension of time periods for exclusive use of data will not assist minor use protection, and, in fact, will actually exacerbate the problem.

The pesticide industry is similar in many ways to the pharmaceutical industry. Under FFDCA, there are limited provisions which grant patent term extension to cover, in part, some of the time lost in the FDA registration process, but it also includes provisions for generic drug registration, the elimination of data compensation provisions, and permits the testing of potential products two years prior to the expiration of the patent. These arrangements create a balanced package for both basic manufacturers and generic drug producers.

Currently under FIFRA we find that in addition to the initial patent, the data used by a generic producer are compensated not at cost but at fully loaded value with market considerations such as early market entry. If Congress selected to extend the patent, in addition to data compensation, the result would be an unfair and inequitable solution that would only drive up the cost to farmers, ranchers, consumers and pesticide end-users. Moreover, it would destroy competition in the marketplace and would disproportionately impact small businesses that formulate or distribute many regional or local products.

We believe that these exclusive use provisions will have a devastating economic impact on formulators and distributors, and significantly increase the costs of pesticides for all farmers, ranches, consumers, and home lawn and garden users.

We believe that these exclusive use provisions should be dropped for the following reasons:

1. It will artificially inflate the costs of nearly all pesticides and create a ten year period where the registrant can maintain a high price for all consumers and pesticide uses. This provision will affect millions of farmers, as well as countless millions of consumers who treat their lawns, shrubs, trees, and gardens.

2. This ten year exclusive use period will broadly affect most food use pesticides, including most of the List A and B food use products currently being reregistered.
3. It will create a monopoly for basic registrants that will deny formulators and distributors an opportunity to market their products for specific minor uses and prevent entry into the market.
4. It will create an economic disincentive to market existing products. For example, dealers and distributors will probably want to carry a product with the largest number of uses, and would not carry a product with 5, 10 or 15 fewer minor uses. In essence, a formulated product with fewer uses would be at a competitive disadvantage in the market place.
5. It would extend protection far beyond the patent term and provide de facto patent term extension.
6. This period of exclusive use would particularly impact old chemicals being reregistered, and could effectively deny formulators and distributors entry into the local and regional markets for minor use products.
7. The provision covers all data which solely supports a minor use. It is not restricted to just residue data.
8. This provision is unneeded and unnecessary because economic incentives for data production for minor uses already exist under the EPA RP Notice 91-8 which provides for protection of data and compensation for that data. The additional economic incentive that exists in an accompanying proposal entitled, "The Crop Protection Minor Use Research and Development Tax Credit Act of 1991," includes a tax credit equal to 50 percent of the qualified data production expenses for that taxable year. This measure provides more economic incentives for all producers of data.
9. This provision has a disproportional economic impact on small businesses that produce, formulate and distribute local and regional products for specific minor uses.
10. Most importantly, this provision reopens the controversial Congressional deliberations over data compensation, generic data registration, patent term extension, and roll-back of the Bolar v. Roche decision that occurred in the 1980's. It devises a program that one-sidedly benefits large basic producers, and creates significant economic disadvantages for small producers, formulators and distributors and denies them an ability to compete in the market place.

CONCLUSION

We at CPDA respectfully urge this subcommittee to hold additional hearings on related FIFRA issues and markup a bill as soon as possible. We strongly support the Lehman - Bliley - Rowland bill (H.R.1627) for its treatment of Delaney, as well as cancellation and suspension. We support H.R.1627, the Dooley Herger bill on public health pesticides. We also urge your support for the yet-to-be-introduced bills by Congressmen Volkmer and Smith on preempting local jurisdictions from regulating the sale and use of pesticides, and Congressman Steve Gunderson's bill on synchronization and coordination of data between Federal and State agencies. In addition, we support Chairman E. "Kika" de la Garza's minor use bill (H.R. 967), except for the provisions on patent term extension and ten years of exclusivity. Finally, we strongly support fixing the registration and reregistration process so that products can be handled in an efficient, effective and expedited manner.

We applaud the subcommittee for its leadership on pesticide issues and look forward to working with you during the 103rd Congress.



The Soap and Detergent Association

TESTIMONY OF GERALD R. PFLUG, Ph.D.

PRESIDENT

THE SOAP AND DETERGENT ASSOCIATION

REGARDING THE STATUS OF ANTIMICROBIAL PRODUCTS

UNDER

THE FEDERAL, INSECTICIDE, FUNGICIDE AND RODENTICIDE ACT

BEFORE

THE SUBCOMMITTEE ON DEPARTMENT OPERATIONS AND NUTRITION

OF

THE HOUSE COMMITTEE ON AGRICULTURE

JUNE 8, 1993

Mr. Chairman and members of the committee, my name is Gerald R. Pflug and I am president of The Soap and Detergent Association (SDA). The SDA is a 139 member national trade association representing the formulators of soaps, detergents and household cleaning products and those companies which supply ingredients to the detergent and cleaning products industry. SDA's members include nationally prominent as well as less well known small, often family-owned, companies. Along with well known formulators of highly visible consumer products, SDA members also include the formulators of industrial and institutional products used in hospitals, nursing homes, hotels, restaurants and public buildings. Over 90% of the cleaning products sold in the United States are made by SDA members.

The products of SDA members have a long history of contributing to the maintenance of public and personal health standards which are, unfortunately, often taken for granted in our country today. Clean clothing, bedding, cooking utensils, plates, silverware, kitchen and bathroom fixtures are, in fact, the broad base on which our exceptional standard of public health rests. The SDA is here today because of its concerns for one of the most important contributors to our high cleanliness standards: antimicrobial and disinfectant cleaning products.

Under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), antimicrobial and disinfectant cleaning products are regulated as pesticides by the Environmental Protection Agency (EPA) because they are intended for preventing, destroying, or mitigating harmful micro-organisms, viruses and bacteria. Common, well-recognized examples of such products include certain brands of

Testimony of G.R. Pflug, Ph.D.
 Subcommittee on Department Operations
 and Nutrition

June 8, 1993

-2-

chlorine bleach (when such claims are made), Lysol Disinfectant Cleaner and Comet Cleanser. Less well known, though equally important, are the myriad commercial products used in business establishments, public accommodations and public buildings.

I am here today on behalf of SDA's antimicrobial/disinfectant products sector because this beneficial category of products faces a number of regulatory problems which we believe ought to be addressed through reform of the FIFRA process. The principal problems of concern are the following:

1. The approval process for new active ingredients needs improvement. No new active antimicrobial agents have been approved in seven years.
2. The process for registering or re-registering products is so cumbersome and attenuated that such processing may require up to two years to complete.
3. Approval of simple label changes may take nine months or more.

The consequence of these regulatory logjams has been to impede the development and introduction of additional safe and efficacious antimicrobial products in the market place. We believe the underpinning for resolution of these regulatory problems already exists in FIFRA.

FIFRA Section 25(a)(1), reads as follows:

Regulations.-The administrator is authorized in accordance with the procedure described in paragraph (2), to prescribe regulations to carry out the provisions of this subchapter. Such regulations shall take into account the differences in concept and usage between various classes of pesticides and differences in environmental risk and appropriate data for evaluating such risk between agricultural and nonagricultural pesticides. (Emphasis added).

If antimicrobial and disinfectant products, as a subset of nonagricultural products, were distinguished under FIFRA and provided a separate regulatory track, we believe that the approval process for these products would be facilitated. Based on reports by our affected members, it seems that informal structures have already evolved within the EPA along the lines we are proposing. These informal arrangements have, however, proven inadequate to resolve the problems faced by the antimicrobial/disinfectant

Testimony of G.R. Pflug, Ph.D.
Subcommittee on Department Operations
and Nutrition

June 8, 1993

-3-

industry. Some increased degree of formalization appears to be required in order to effect the process efficiencies required.

Further, it seems to us that the establishment of a separate antimicrobial regulatory track would benefit the EPA as well as industry by clarifying standards and establishing an effective division of labor in the FIFRA regulatory approval process.

While I wish that I could offer you a comprehensive solution to the issues of our concern, I cannot do so today. I am pleased to tell you, however, that the SDA is currently working to develop a more concrete proposal for your consideration along with allied associations.

Mister Chairman and members of the Committee. this concludes my formal remarks. The SDA appreciates the opportunity to be here today and I would be pleased to answer any questions you might have at this time. Thank you.

STATEMENT

OF

William C. Balek
Director of Legislative Affairs
INTERNATIONAL SANITARY SUPPLY ASSOCIATION

before the

Subcommittee on

Department Operations and Nutrition

Committee on Agriculture

United States House of Representatives

June 8, 1993

I. INTRODUCTION

My name is William C. Balek and I am the Director of Legislative Affairs for the International Sanitary Supply Association. ISSA is a non-profit trade association comprised of over 4,000 members located across the country. The majority of these companies are considered small businesses. Over 60% of these companies have annual gross revenues of less than \$2 million and have 10 or less employees.

These companies manufacture and distribute a broad variety of institutional and industrial cleaning products, including antimicrobial pesticide products such as disinfectants, sanitizers and germicides which are governed by the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). These products are used by hospitals, nursing homes, schools, food processing plants, hotels, restaurants and other institutional and industrial establishments. As such these products play an important role in the maintenance of sanitary and healthful conditions.

ISSA appreciates this opportunity to testify and we thank Chairman Stenholm and the Subcommittee for conducting this hearing. Our statement addresses several issues: expedited registration; maintenance fees; the Public Health Pesticide Protection Act (H.R.1867); preemption of local jurisdiction; coordination and synchronization of data requirements; and certification and training.

II. EXPEDITED PROCESSING OF REGISTRATIONS

ISSA encourages Congress to explore options to ensure that the expedited registration provisions of the 1988 amendments to FIFRA, also known as fast track registration, is properly implemented. Fast track registration requires EPA to expedite the processing of product

registrations that are identical or substantially similar to existing pesticide products and for which no scientific review of data is required. Under this expedited process, EPA is required to approve or deny the application for registration within 90 days of receiving a completed application.

In fact, it is rare that this ninety day deadline is met by EPA. Our membership has pointed out numerous instances where it has taken six months to well over one year to process their fast track registration. This delay creates an anticompetitive situation, especially for a small company whose only advantage may be the speed with which they can bring a product to market. More importantly, this situation denies the public the benefit of new and improved products.

ISSA was an ardent supporter of the fast track registration system during the 1988 reauthorization of FIFRA. Our support was based on the fact that many relatively simple registrations were not being processed in a timely manner. In 1988, EPA had a tremendous backlog of "me-too" registrations and those amendments not requiring scientific review, when, in fact, these registrations could be processed in a fraction of the time. In some cases, only a few days of attention were necessary. But because of EPA's priorities, these registrations were assigned a low priority.

Today, approximately five years after enactment, fast track registrations are still not processed in an expeditious manner. The ninety day deadline is the exception and not the rule as it should be.

We encourage you to direct EPA to improve its management of the registration process. We ask that EPA be required to designate specific personnel on each product manager's

registration team to work on fast track registrations. Perhaps even a color coded application for fast track registrations could be used so that they could be more easily recognized than by the current system.

III. MAINTENANCE FEES

ISSA opposes increases in pesticide maintenance fees or a provision that would extend EPA's authority to levy such fees.

As part of the 1988 FIFRA amendments, Congress provided EPA with the authority to raise \$14 million a year in registration fees over the course of the nine year reregistration program, in addition to a one time fee on active ingredients.

We opposed the imposition of fees at that time because we believed it would result in a significant reduction in the number of registered products. In fact, there was an approximate 50% reduction in overall product registrations. The decline in overall product registrations resulted in a shortfall of the annual goal of \$14 million which sparked another round of increases in fees.

The adjustments to the maintenance fees ultimately resulted in reaching the statutory goal. However, EPA is once again seeking additional revenues to finance the reregistration program.

ISSA opposes increases in pesticide maintenance fees or a provision that would extend EPA's authority to levy such fees. Moreover, ISSA opposes any fee provision that does not take into account small business consideration or low-volume products. Since 1988, annual maintenance fees have increased from \$425 to \$1350 and fee limitations or "caps" have almost tripled. The costs have placed substantial burdens on small formulators of antimicrobial

pesticide products and have caused industry to cancel the registration of numerous products drastically altering their product mix and marketing strategies. Before we consider any fee provisions, we must ensure that the sensitive economic conditions that exist in the industry are taken into account.

IV. PUBLIC HEALTH PESTICIDES PROTECTION ACT (H.R.1867)

ISSA supports the Public Health Pesticides Protection Act, H.R. 1867, because it recognizes the important role antimicrobial pesticides play in maintaining safe and sanitary conditions. The Public Health Pesticides Protection Act, H.R. 1867, was introduced to provide recognition and relief for pesticides registered for public health purposes. The legislation would extend special consideration and protection to pesticide products used to maintain good mosquito and other vector programs. In addition, H.R. 1867 would extend the same special treatment to certain disinfectants, sanitizers, germicides and other similar products.

H.R. 1867 is supported by ISSA because it recognizes the importance of these products in maintaining safe and healthful conditions in society. These products, however, have experienced tremendous regulatory burdens because they are treated just like agricultural pesticides in many cases. These burdens have become so substantial that many products have been dropped from the market because it is no longer economically feasible to maintain their EPA registration. As a consequence many products essential to the maintenance of safe and healthful conditions will continue to be dropped from the market unless some relief is provided.

H.R. 1867 provides that relief. Specifically, H.R. 1867 would make the following amendments to FIFRA:

1. The bill would define "public health pesticides" in the context of minor use to include a pesticide which is used in the prevention or mitigation of viruses, bacteria, or other microorganisms (other than viruses, bacteria, or other microorganisms on or in living man or other than living animal) that pose a threat to public health.
2. H.R. 1867 would exempt pesticides classified as "public health pesticides" from reregistration and annual maintenance fees.
3. The bill would create a separate class of pesticide registration for public health pesticides with a risk benefit analysis, separate and distinct from that utilized for agricultural pesticides.
4. The legislation would expedite the registration of products necessary for public health protection.
5. H.R. 1867 would require EPA to take into consideration the differences in "concept and usage" between agricultural, non-agricultural, and public health pesticides.
6. H.R. 1867 would require EPA to consult with the Secretary of Health and Human Services on pesticides for public health uses similar to the existing consultation between EPA and USDA.

For these reasons we encourage your support of H.R.1867.

V. PREEMPTION

ISSA supports the preemption of local jurisdictions below the state level in regard to the

regulation of the sale or use of pesticide products. We strongly support and encourage Congress to adopt legislation which would ensure that pesticide regulation is maintained entirely by a partnership of federal and state governments.

The Supreme Court ruled in Wisconsin Public Intervenor v. Mortier that the more than 83,000 local jurisdictions nationwide may adopt their own pesticide regulations. The Court stated that while FIFRA establishes a strict and complex federal/state process which governs the sale and use of pesticides, the statute does not preempt political subdivisions of a state from regulating the same products. The ramifications of this decision are potentially devastating for suppliers and users of pesticide products.

The issues surrounding pesticide regulation are complex and demand a high level of expertise and resources. The regulation of pesticides requires a careful balancing approach which takes into consideration the potential adverse environmental impact as well as the benefits provided by the product in question. Most local jurisdictions, however, simply do not have the scientific and technical resources necessary to address these issues effectively. Consequently, local politics or public hysteria may be substituted for sound scientific reasoning as a basis for local pesticide regulations. Regulations that are issued under such conditions, although well intentioned, often fall short of their goal while at the same time placing unreasonable burdens upon industry.

The industry is now confronted with the possibility of thousands of local jurisdictions adopting pesticide regulations that are conflicting with each other and/or inconsistent with state and federal laws. In fact, since the Supreme Court's decision, numerous local jurisdictions have adopted various pesticide regulations. It is extremely difficult if not impossible for companies,

especially small businesses, to market their products under such confusing conditions. Such local regulation will only serve to seriously impede interstate as well as intrastate commerce.

Unreasonably burdensome and conflicting regulations will result in the reduced availability and use of pesticide products such as sanitizers, germicides and other antimicrobial pesticides. These products are essential to the maintenance of sanitary and healthful conditions in countless numbers of institutional and industrial establishments. The reduced or non-use of these products will hinder our ability to control the spread of harmful microorganisms and bacteria.

ISSA supports pesticide regulation that addresses specific local needs when justified on a rational scientific basis. It is important, however, that these decisions be made by a federal and state partnership to ensure that sensible and uniform regulations are issued on the basis of sound scientific judgment. To do otherwise would eventually deny the public access to pesticide products essential to the maintenance of sanitary conditions.

VI. COORDINATION AND SYNCHRONIZATION OF PESTICIDE DATA REQUIREMENTS BETWEEN EPA AND THE STATES

ISSA supports legislation which would facilitate the coordination and synchronization of data between the states and the U.S. Environmental Protection Agency. Such coordination is essential to avoid redundant testing and unnecessary expense.

The current problem is exemplified by the situation in California. California's Birth Defects Prevention Act, (S.B. 950), requires the filling of data gaps for all pesticides including antimicrobial products. In order to implement S.B. 950, California adopted a definition of a

"data gap", established a list of tests needed to be completed, and set a time table for filling these gaps. In so doing, the state has disregarded the efforts of Congress in establishing its own expedited reregistration program in the 1988 amendments to FIFRA, which were designed to fill the same data gaps.

In effect, California has established an agenda and time table that duplicates and conflicts with federal requirements, resulting in unnecessary, repetitive and redundant testing which consumes valuable time and resources and actually delays the closing of data gaps. If left unaddressed, this problem will surely expand. At least one state, Arizona, has enacted similar legislation, and a few other states are considering similar measures.

The additional and conflicting data requirements artificially raise the cost of manufacturing and distributing pesticide products. These additional costs have already resulted in the cancellation of numerous antimicrobial pesticide registrations within California. This pattern is likely to continue as other states enter the picture, causing other useful disinfectants and other antimicrobials to be taken off the market.

Therefore, ISSA strongly encourages Congress to explore legislation that would facilitate the coordination and synchronization of data requirements between the states and EPA. Such legislative action will help stabilize the cost of pesticide products by precluding unnecessary or redundant testing, ensuring their continued availability on the market.

VII. LABEL CHANGES

ISSA strongly encourages legislation that would require EPA to coordinate the many different label changes required by the Agency. Presently, several different offices and

programs within EPA require modifications to existing pesticide product labels. Unfortunately, there is no internal coordination of these various label changes. EPA requires, at various times, numerous modifications to existing labels. The changes might reflect a new active ingredient, an inert or a different use. Other changes are made to incorporate a new set of directions or warnings about use or specific health and safety instructions. At other times, EPA may require the label to be modified to include new instructions for proper disposal of the container. In addition, specific programs within the Agency address specific changes to labeling contents. For example, the Label Improvement Program requires various modifications to label contents.

In essence, many different offices and programs within EPA require registrants to alter their labels. However, there is no mechanism in place through which the Agency is able to coordinate these various label changes. As a consequence, companies may modify their label to address one program's requirements, only to find several months later that they must, once again, alter their label to address another EPA requirement.

This is especially problematic for ISSA members who formulate and distribute private label products. For example, one formulator holds over 100 product registrations that are each sold under 20 to 30 different private labels. Consequently, one label change required by EPA therefore results in the printing of thousands of new labels, only to find that another program or department requires additional changes several months later. This lack of coordination often results in the company discarding thousands of dollars in labels because they are made obsolete by another EPA directive.

ISSA, therefore, recommends that several changes be made in the Agency's labeling policy to avoid these complications. First, we suggest that EPA establish one office within the Agency that would be responsible for coordinating all label changes required by the various programs and divisions within EPA. Secondly, we recommend that EPA select one date a year

in which all label modifications are required. These suggestions should provide EPA with sufficient flexibility to respond to a crisis or other situation that would require an immediate change to be made to the label.

In our opinion, these suggestions, if adopted, would be consistent with EPA's need to monitor and revise labeling as well as ease the burden placed upon industry.

VIII. CERTIFICATION AND TRAINING

In past years, legislative proposals have been made that would amend FIFRA to extend certification and training requirements for those who apply restricted use pesticides to those who as a part of their job, apply general use pesticides, including antimicrobial products such as disinfectants, sanitizers and germicides. ISSA strongly opposes such broad based training as unnecessary and extremely burdensome.

Such a broad based certification and training program would literally require maids, janitors, cleaning personnel, building maintenance people, apartment managers, etc. to undergo extensive training so that they could lawfully apply products comparable to Lysol, Pine Sol or a toilet bowl cleaner registered as a disinfectant. These products certainly do not present the same dangers that restricted use pesticides do, and therefore, do not require the same type of training. In fact, many of these products are virtually identical to those used in homes by the general public. It makes no sense to require the employees of a homeowner to undergo such extensive training to apply a disinfectant bowl cleaner, when all the homeowner is required to do is to follow the directions.

In addition, institutional and industrial employees who apply disinfectants, germicides and other similar products already receive comprehensive education and training regarding safe application and use. The OSHA Hazard Communication Standard applies to virtually all

chemical products used by any employee, including antimicrobial pesticides. The Standard requires employers to train and inform their workers of:

- Methods and observations that may be used to detect the presence or release of a hazardous chemical in the workplace;
- Physical and health hazards of the chemical products in the work area;
- Measures employees can take to protect themselves from these hazards, such as appropriate work practices, emergency procedures, and personal protective equipment to be used;
- Details of the hazard communication program including an explanation of the labeling system and material safety data sheets (MSDSs), and how to use the material properly;
- Operations in their work area where hazardous chemicals are present; and
- The location and availability of the written hazard communication program including the list of hazardous chemicals and file of MSDSs.

This comprehensive approach created by OSHA is more appropriate for institutional and industrial users of pesticide products because of the wide variety of chemical products they encounter in the workplace. Institutional employees utilize a broad spectrum of products to clean and maintain their facilities, such as general purpose cleaners, air fresheners, carpet shampoos, floor finishes and strippers, degreasers, oven cleaners, as well as disinfectants, germicides and other products registered as pesticides. Many of these products present more dangers than do the institutional pesticides, and yet OSHA training is deemed adequate for those products. More importantly, by singling out institutional pesticides for "special attention", we would be sending an erroneous message to employees: that those pesticide products are more dangerous than other chemical products found at the workplace, when, in fact, this perception would be false in many cases. Such special attention could cause employees to be less careful when handling non-pesticide chemical products, thereby increasing the potential for a job related injury.

ISSA, therefore, opposes a broad based certification and requirements that would affect institutional and industrial users of general use pesticide products.

IX. CONCLUSION

ISSA thanks you for this opportunity to discuss issues of importance to our industry. We welcome your comments and look forward to working with you in the FIFRA reauthorization process.

Statement of Richard Rominger, Deputy Secretary
United States Department of Agriculture
before the
Subcommittee on Departmental Operations
and Nutrition
House Committee on Agriculture
June 8, 1993

Good afternoon, Mr. Chairman and Members of the Subcommittee. I very much appreciate the invitation to present the Department's views on pesticide registration and reregistration, including the consequences of strict enforcement of the Delaney Clause, minor use pesticide concerns, and reduced-risk pesticides and how all of these relate to the American consumer and American agriculture.

Pesticide policy is a major focus of the Administration. We fully recognize the need for action. Over recent weeks, there have been numerous discussions between the Department, the Food and Drug Administration and the Environmental Protection Agency. We are continuing to meet with the goal of refining an Administration position on pesticide regulation and related issues. The Department has been, and will continue to be, a full participant in these discussions.

I believe we can agree that the Federal Government must regain the confidence of the public that it is protecting American consumers and the environment from problems linked to the use of pesticide chemicals. The loss of important food use pesticides can result in heightened risk of disease-causing

organisms in food, food price increases, adverse effects on food quality and its acceptability, and reduction in the availability of nutritional food choices. To make the best decisions, we need to make revisions in two statutes that control pesticide use: the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA).

Changes to these laws must consider the following five objectives:

1. Public Health Protection. Harmful exposure of the public to pesticides in the food supply must be prevented.
2. Restore and build public confidence. Ensure that the food supply for Americans continues to be safe.
3. Provide appropriate oversight of pesticides and pesticide use. Prevent the use of pesticides with unreasonable risks and develop safe alternatives.
4. Streamline pesticide regulation so pesticide producers and users can understand and comply with pesticide and food safety laws, and still have the necessary tools to produce and deliver safe food to the American consumer.
5. Protect the Environment.

We commend you and the Committee for holding this hearing and hope that with the collective efforts and wisdom of the Congress, the Executive Branch, consumers, the agricultural production sector, public interest groups, and the agrochemical

industry, we will be able to achieve workable reform to the laws regulating pesticides and food safety.

The responsible use of pesticides by food producers and distributors has played an important role in providing a safe, available, abundant, and affordable food supply for the American consumer and for part of the world. Agriculturalists, many of whom can also claim to be environmentalists, have used pesticides as an effective tool to provide food and have enabled our domestic food system to be easily managed. We also recognize that there must be continuous improvement to that food delivery system, acknowledging that there is a shared responsibility for consuming and producing food. Those shared responsibilities must also blend with the shared goals of public health and environmental protection to reaffirm that our food supply is safe.

The registration and reregistration processes are incredibly important to both the shared responsibilities and the shared goals of pesticide regulation. These regulatory processes are extremely complex and increasingly costly to the agricultural sector, to the regulatory community, and to the consumer. These processes demand that we make the best regulatory decisions possible, using state-of-the-art science, and good public policy. Mr. Chairman, the sciences of risk assessment, toxicology, and analytical chemistry have changed much faster than the

understanding of pesticide risk. Medical and public health sciences are constantly evolving. EPA must have the flexibility to adopt these changes and use them in risk assessment and risk management. EPA must also have the ability and resources to act promptly and effectively, based on the best scientific information, to deal more credibly with problem chemicals and thereby help restore public confidence in pesticide regulation.

Cancellation. USDA strongly supports a streamlined approach in the cancellation process of a pesticide chemical for EPA. We also support early, frequent, and meaningful consultations in all cancellation activities, and support appropriate interaction with EPA, FDA, USDA, consumers, producers, and the agrochemical industry in such matters.

As stated by the National Academy of Science in "Regulating Pesticides in Food--The Delaney Paradox," central to pesticide regulation is the registration process, and this process is linked with the setting of tolerances in food. Tolerance setting has proven to be more complex and troublesome since the Ninth Circuit Court's decision in Les v. Reilly. The Court ruled in this case that under the Delaney Clause EPA "has no discretion" to establish pesticide tolerances that allow pesticide residues to be present in processed foods at levels greater than the pesticide tolerances allowed in the raw agricultural commodities if the pesticide "induces cancer in animals," regardless of how

small the risk. Applying the Court's decision, EPA has revoked five emergency exemptions it had granted previously and denied 16 other emergency requests for special pesticide usage even though EPA, FDA and USDA continue to believe that the pesticides affected by the Court decision pose only a negligible risk to public health. Tolerances must now be denied for some agricultural products that would otherwise be permitted under FIFRA. The alternative to the Delaney standard would be a more practical standard of "Negligible Risk."

Minor Use Pesticides. Mr. Chairman, we commend you and appreciate your interest in addressing minor use pesticides. Vegetables, fruits, nuts, trees, ornamentals, herbs and turfgrass are often referred to as minor crops even though those crops account for about 40 percent of the dollar value of all agricultural production. There are also a number of minor uses on major crops that require special pest control treatment. A recent publication was titled, "Pesticides-Minor Uses/Major Issues," but we hear from growers it is more like "Minor Uses/Major Problem." We are continually made aware of food production problems stemming from minor use pesticide products being "dropped" or canceled. Tied to the registration and reregistration process, agrochemical companies cannot justify costs of producing data and conducting studies for a pesticide that will never recapture those costs. I am sure you are aware of the many pesticide registrations that have already been

canceled, and we do not have a problem with many of those cancellations of pesticides that were seldom if ever used. But, as a result of the current reregistration efforts, many more minor use products are not being supported by the pesticide manufacturers. As the number of products diminishes for minor uses, the remaining pesticides are used more, and pest resistance to those products increases. Scientists agree that pest resistance is best managed through a variety of products with diverse mechanisms for control of the pest. Increased use of a single product, or products with a similar control mechanism, can lead to a serious situation where there are not products available that are effective, or the amounts used must be increasingly large, and thus present greater human and environmental exposures.

USDA supports expedited registration of biological pest control agents by EPA.

USDA has facilitated the Minor Use Working Group since 1990 to discuss and recommend new approaches for reregistration decisions impacting upon minor crops. The members of this group include USDA, EPA, chemical manufacturers and associations, and growers. An information system has been developed to rapidly and efficiently disseminate information from manufacturers to growers concerning minor use products to be canceled. This more timely information helps growers plan their production strategy and

manage their crop more effectively.

USDA has approached the minor use problem through support of the IR-4 program. The IR-4 Project, headquartered at Rutgers University, is a national program established in 1963 for the clearance of chemical pesticides and biorationals for minor and specialty crops and animal drugs for minor uses. The IR-4 Project coordinates directly with Federal regulatory agencies (especially EPA and FDA), industry, and crop producers. IR-4 has been expanded to include pest control activities in the biological pesticide area, a new direction where researchers and growers are optimistic for new pest control mechanisms.

In 1989, USDA initiated a multi-agency effort to collect and analyze pesticide use and residue data regarding actual levels in food, beginning with fresh fruits and vegetables. This program is providing EPA with data that is important to reregistration efforts.

Reduced Risk Pesticides. USDA continues to be supportive of the development of products that pose fewer risks to humans and the environment. USDA research, both chemical and non-chemical, has as its objective more efficient and effective pest controls without great risks. USDA supports the registration of pesticides that can be used effectively with less risk, and supports any waiver of data requirements that EPA deems

appropriate along that product's registration journey.

CONCLUSION

The Department will work together with EPA and FDA to effectuate appropriate changes in our existing pesticide regulations that will enhance food safety, yet preserve the viability of the agricultural industry.

Mr. Chairman, this concludes my statement. I will be glad to respond to any questions the Committee may have.

TESTIMONY OF
VICTOR J. KIMM
ACTING ASSISTANT ADMINISTRATOR
OFFICE OF PREVENTION, PESTICIDES, AND TOXIC SUBSTANCES
U.S. ENVIRONMENTAL PROTECTION AGENCY
BEFORE
SUBCOMMITTEE ON DEPARTMENT OPERATIONS AND NUTRITION
COMMITTEE ON AGRICULTURE
U.S. HOUSE OF REPRESENTATIVES
JUNE 8, 1993

I. INTRODUCTION

Good morning Mr. Chairman and members of the Subcommittee. I appreciate the opportunity to testify before you today on the need to effectively address the important issues related to pesticides and food safety. This Administration is pursuing legislative and administrative changes to enhance consumer protection from pesticides. The new Administration realizes the necessity of, and is committed to, formulating new approaches to protect consumers from pesticide risks. We want to ensure that our regulatory decisions are sound, timely, and can be administered and enforced in a consistent manner that protects public health and the environment, while providing for an abundant and affordable food supply. Thus, the U.S. Environmental Protection Agency, working in concert with the White House Domestic Policy Council, the White House Office of Environmental Policy, the U.S. Department of Agriculture, the Food and Drug Administration, the Department of Justice, the Congress, and interested parties, is taking steps to achieve these goals.

The major EPA programs to protect public health and the environment from the adverse effects of pesticides remain the registration of new chemicals and new uses of pesticides; the reregistration of old chemicals; and the establishment of tolerances (maximum permissible residues associated with approved uses) that make up the basis for this complex licensing program. Also, I will report on the Agency's schedule to implement the Ninth Circuit U.S. Court of Appeals' decision

on the Delaney clause, which could have a substantial impact on the agricultural community. Given the breadth of subjects covered in this testimony, I plan to report on our progress in implementing the program.

II. REGISTRATION ACTIVITIES

The Agency faces a daunting task of keeping up with the extraordinarily large workload that comprises the registration program. In a typical year, EPA receives approximately 20 applications for registration of pesticides with completely new active ingredients, 220 petitions for tolerances, 900 applications for pesticides that resemble products already on the market ("me-toos"), 45 new uses of old pesticides, 5,300 other amendments to existing product registrations, 115 experimental use permit applications, and 350 requests for emergency exemptions. In other words, to stay current with this flow of submissions, EPA must make around 27 regulatory decisions a day, many of which involve the review of large bodies of scientific data. We have tried to both identify and respond to emerging trends and find ways to apply our resources more efficiently.

Biologicals and Biotechnology. Biological pesticides comprise the single fastest growing segment of registration activity within the Office of Pesticide Programs (OPP). The term "biologicals" includes three distinct types of pesticides: microbials, biochemicals, and plant pesticides. Microbials are living organisms, whether natural or genetically engineered, and include bacteria, protozoa, fungi, and viruses. Biochemical pesticides include hormones, pheromones, and enzymes. Plant pesticides, the latest class of products being developed for eventual registration are the pesticidal substances produced by plants, including plants that have been genetically engineered. Since the first biological pesticide, *Bacillus popilliae*, was registered in 1948, EPA has registered approximately 30 microbials and 50 biochemicals, and over 200 such products are now on the market. Prior to

1985, registration of biologicals was rare, comprising at most 10% of all pesticides. In 1991, 70% of all new pesticidal active ingredients registered were biologicals; in 1992, the share was 50%.

Compared to conventional synthetic chemicals, biological pesticides represent a fundamentally different class of products. Regulating them requires new and innovative approaches because they do not fit nicely into our established regulatory scheme for conventional synthetic chemicals. Some of the innovations include unique and significantly reduced data requirements arranged in a tiered testing scheme. Moreover, the tests are tailored to the inherent characteristics of biologicals. For example, microbials must be tested for product survival and replication in the environment -- characteristics which are of no concern for conventional synthetic chemicals. This approach ensures that only the minimum data necessary for scientifically sound regulatory decisions will be required.

EPA is committed to encouraging the development and use of environmentally acceptable biological pesticides as alternatives to more toxic and persistent conventional chemical pesticides. New applications for registration or experimental use permits of biologicals are reviewed expeditiously in order to get these products on the market sooner. The processing time for the registration of a new biological pesticide is generally 6 to 18 months, as compared to 2 to 3 years for a conventional pesticide. Therefore, the time and cost to register a biological pesticide are significantly less than for conventional chemicals. Nonetheless, we are actively working on other projects to improve both the scientific foundation and efficiency in our efforts to regulate biologicals.

For example, in FY '92 Congress earmarked \$175,000 for biological pesticides regulatory projects. These monies went to projects such as workshops on risk assessment for plant pesticides and on risks associated with large-scale use

of *Bacillus thuringiensis*, or *Bt*, and streamlining the review of biological submissions and development of test protocols.

Pheromones. We are also looking for ways to reduce even further the regulatory requirements for pheromones. A pheromone is a chemical produced by an animal that modifies the behavior of other individuals of the same species. The use of these biochemicals to attract and trap, or disrupt the mating of insects has been a successful pest management technology for a considerable period of time. However, current regulations may be burdensome and can impede pheromone research and development. EPA is considering regulatory relief under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA) for pheromones contained in solid matrix dispensers (e.g., twist ties and plastic tapes) with the goal being to facilitate market entry and to promote their integration into pest management strategies by easing the testing requirements for these products or possibly eliminating the registration requirement for certain products.

Microbials. At the same time, we are proposing to tighten our regulatory controls over certain microbial products deemed to potentially pose a significant risk. Microbial pesticides achieve their effects in a number of ways. For example, they may produce a substance that exerts a toxic effect, act as pathogens that cause disease in the organisms they infect, or outcompete and displace the pest. Because of the likelihood that natural control mechanisms will limit microbial pesticides, the Agency has generally presumed that the relatively small amounts used in small-scale testing would not pose any significant risks.

It is now possible, however, to genetically modify microbial pesticides that express new pesticidal properties, and that may not be subject to these natural limitations. This past January, EPA published a proposal to amend its experimental use regulations for microbial pesticides to clarify the circumstances under which an

experimental use permit is presumed not to be required. As part of this amendment, we propose to require notification before the initiation of small-scale testing of certain microbial pesticides, thus giving EPA the ability to scrutinize these products before they are released into the outdoor environment. This proposal represents a refocusing of our concern and, in many respects, actually reduces EPA's review of certain currently covered microbial products.

Plant Pesticides. Some of the most recent advances in biotechnology are in the field of plant pesticides. The Agency is concerned about the potential for effects on human health and the environment caused by the pesticidal substances which could be produced by genetically engineered plants. Therefore, we are developing a proposed policy for the regulation of plant pesticides, including transgenic plant pesticides. EPA will address the regulatory status of pesticidal substances produced by plants, under FIFRA and FFDCA and, describe the scientific considerations the Agency will use to evaluate these plant-pesticides. Until this policy is final, we are addressing plant pesticide products on a case-by-case basis. We have already granted two applications for experimental use permits, for pesticides produced by cotton and potatoes, and a third, by corn, is pending.

In summary, we are learning as we go. As we gain experience in regulating biological pesticides we can make better regulatory decisions. Our goal now is to establish a credible, predictable, and efficient regulatory pathway for these products.

Expedited or "Fast-Track" Reviews. EPA is pursuing expedited processing of registration applications for administrative amendments and for those pesticides substantially similar to registered pesticides also known as "me-too" registrations. We have set up a Quality Action Team in an effort to reduce significantly or

eliminate the "me-too" and amendment fast track backlog and improve the Registration Division's ability to meet the 90-day processing time established in the statute. The program has adopted a number of procedures intended to make best use of available resources and improve efficiency. These include careful and prompt screening of all incoming materials, organizing and grouping related items for scientific review, and constant, accurate maintenance of records and computerized tracking. The definition of fast track eligibility has been clarified to include only actions that can be processed on the product management team level. EPA will shortly publish a notice to industry urging them to organize and group incoming materials to facilitate the Agency's streamlining efforts.

When FIFRA '88 mandated that EPA give expedited review to "me-too" registrations and minor registration amendments, EPA had an enormous backlog of such applications. Since then, the Agency has made significant strides toward meeting the timeframes outlined in the FIFRA 1988 amendments. The number of old chemical amendments waiting to be processed has dropped from 419 in FY '89 to 199 today (53% decrease). In the same time period, the backlog in processing "me-too" applications has gone from 858 to 480 (44% decrease). Average processing time was cut from approximately 180 days to 88 days, and the percentage of applications that are processed within the mandated time frame has risen from 48% to 63% for "me-toos" and has remained steady at 75% for amendments. During FY '93, OPP made a risk based decision to focus its limited resources into doing registration and reregistration activities while trying to hold the backlog at the 1992 level (Charts 1 and 2).

Congress approved the spending of up to \$2 million per year from the FIFRA revolving fund for the processing of Fast-Track old chemicals and amendments in the required 90-day time frame. At the end of FY '92, we had spent \$4.1 million

in intramural funds which covers the salaries of 68 full-time equivalents (FTEs) and other expenses, and \$1 million in extramural funds which paid for the salaries of part-time help from the American Association of Retired Persons (AARPs). This totals \$5.1 million from the end of 1989 through 1992 averaging about \$1.5 million per year.

Reduced-Risk Policy Initiative. With rapidly advancing technologies and the growing interest in Integrated Pest Management (IPM), sustainable agriculture, biological pesticides, and even organic production, it is important that we realize that these forces are changing agriculture and pesticide use in fundamental ways. Not only is the public, as you know well, demanding a safer environment, but farmers, too are becoming more attuned to matters like the quality of their groundwater and their soil. The philosophy that any pest problem can be solved with the use of a chemical is no longer the conventional wisdom.

To respond to these forces, EPA has set a goal of promoting safer methods of pest control. Under the new Administration, Ms. Browner hopes to encourage the replacement of chemical-intensive agricultural practices with informational-intensive and technology-intensive practices. Not only can such changes improve environmental quality, but it will increase agricultural yields and profits, as well. EPA hopes to continue and broaden our cooperation with USDA toward this goal. In sum, Ms. Browner hopes that this new emphasis will have a positive impact on the farmer's culture, livelihood, and way of life.

As EPA has examined its role in promoting safer pest control, we realized that our current regulatory program created barriers and provided few incentives for the development and use of safer pesticides. Now, both EPA and the agricultural chemical companies are responding to public concerns to reduce pesticide related risks and to prevent agricultural pollution by the development and

use of less toxic pesticides.

With the inception of our Reduced-Risk Pesticide Policy Initiative, announced last spring, EPA has begun a long-term effort to create incentives for the development, registration, and use of reduced-risk pesticides and, at the same time, encourage the replacement of higher risk pesticides for which no alternatives are currently available. The program was announced in the *Federal Register* in July, 1992 and a public workshop was held the following October. Over 200 people attended the 2-day workshop and we received over 170 comments, ideas, and suggestions. Because of the overwhelming interest, we are planning another workshop which is scheduled for the first quarter of Fiscal Year 1994.

Our plan is to implement an interim strategy while a more formal policy is being developed. Our short term approach is to let the applicant tell us what it thinks is a reduced risk pesticide. We hope to capitalize on good ideas that can be executed quickly. A draft policy statement, currently undergoing public comment and interagency review, announces that in scheduling the review of pesticide applications involving new active ingredients, one of the factors EPA will consider is the opportunity for reduced risk. The Notice would provide general guidance to the registrants on the types of supportive information they should provide if they feel that their product offers opportunities for risk reduction. By adopting this voluntary pilot program, EPA can test its feasibility, obtain additional comments from outside sources, and improve the Agency's ability to devise a long term strategy which will include new uses of already registered pesticides.

To develop a more comprehensive reduced-risk policy, EPA's long term strategy will focus on these major themes which came out of the workshop:

1. Developing Criteria. EPA intends to establish a list of criteria for identifying a reduced risk pesticide. These criteria will be science-based to provide

assurance of protection of public health and the environment, and will be sufficiently objective that incoming pesticide applications may be screened quickly to identify lower risk candidates before the detailed review begins. EPA intends to work with the public -- industry, academia, and public interest groups -- to develop the criteria. Our fall workshop will be the vehicle for public discussion and will focus specifically on this aspect of the policy.

2. Streamlining the Registration Process. EPA currently has in place several teams whose charge is to analyze the registration process to recommend efficiencies. The streamlining sought will affect all incoming actions and not be limited to those claiming lower risk.

3. Pesticide Label Reform and Informational Outreach. In order to encourage pesticide users to choose reduced risk pesticides, EPA is considering revising its pesticide labels. Several workgroups within the Agency are addressing the complex and multifaceted issues which arise with labeling. EPA will also consider other mechanisms to reach interested persons with improved information about pesticides that may affect them, other people, or the environment in general. The Agency plans to improve the informational content of pesticide labels and to develop other educational media, e.g., pesticide fact sheets and training programs to permit more informed choices by users and other affected parties. In addition, the Agency is considering allowing certain comparative safety claims in labeling and advertising materials to better inform users of the relative risks of pesticide products.

Reduced-Regulation Initiative. EPA is aware that among the tens of thousands of products it regulates as pesticides, there are some which are generally benign in nature and are widely used in non-pesticidal circumstances. Because of increased interest in natural and environmentally-friendly pest control

measures, more substances are being employed as alternatives to synthetic chemical control methods. Many of these substances generally pose negligible risks yet require substantial resources to regulate. Although EPA historically has exercised its authority over virtually all types of pesticides, the Agency is now reconsidering whether the burdens, particularly on small business, resulting from regulating such products are warranted. At present we believe that the cost and effort expended by both the applicant and the Agency do not add meaningfully to protection of public health or the environment.

Therefore, EPA is exploring approaches to reduce or eliminate the regulatory requirements for those products, where it can be accomplished without posing unreasonable risks to human health and the environment. For example, EPA is writing a proposed rule to exempt from FIFRA certain uses of natural cedar products, e.g., wood, blocks, chips, and needles. We are also identifying other potential candidates for exemption or reduced regulation, and will pursue additional rule-making aimed at providing regulatory relief for a growing number of biologically-based substances and low-risk pesticides. EPA is also soliciting public suggestions and recommendations for candidates in this area. We hope that this initiative will provide an opportunity to relieve some small businesses of unnecessary regulatory burden, reduce EPA's workload without compromising public safety, and free up valuable resources for more promising ventures.

II. REREGISTRATION PROGRESS

I would like to turn now to reregistration. We have made reregistration of older pesticides a priority since the passage of the 1988 FIFRA amendments, when Congress called for the establishment of a five step process to bring up to current standards the testing supporting the continued licensing of all pesticides originally registered prior to 1988. We have already made significant progress in many

areas, significantly reducing risks from a number of different pesticides. These amendments also have been a significant factor in reducing the number of active ingredients and products to be reregistered. Moreover, we believe "the pump is primed" for steady reregistration decisions over the coming years. We still face a huge amount of work for which additional funding is needed. Let me describe the situation in more detail.

Reregistration Case Decisions and Product Reregistration. A few years ago it was popular to say that EPA had not reregistered any pesticides. But, as of today OPP has made 31 reregistration case decisions through Reregistration Eligibility Documents (REDs), covering 47 pesticide active ingredients. Another 17 REDs will be issued by October. The RED is EPA's major risk decision point for pesticides, since it evaluates risk concerns for all health and environmental end points of a particular chemical or group of chemicals.

In 1988, there were 611 reregistration cases covering 1,153 individual chemicals and almost 50,000 products to be reregistered. Because of EPA's thorough and timely implementation of statutory fees and follow-up to ensure registrant commitments to support cases, there remain only 405 cases, covering fewer than 700 pesticides, and around 20,000 products subject to reregistration. In most cases, these pesticides have been dropped for economic reasons, because the cost of fees and data development outweigh expected income.

RED decisions are only the first step in reregistration. Approximately 18 to 24 months after a RED is issued, EPA makes decisions on the individual products containing the active ingredient. Of the approximately 20,000 products subject to reregistration, about 2,250 are associated with the 31 REDs issued to date. Of these we have formally reregistered 33 products, while almost 600 have voluntarily canceled or have been forwarded for suspension action for failure to

submit required data (refer to Chart 3).

Continuous Risk Reduction. While it is helpful to count the number of RED decisions EPA makes as a measure of progress, let us remember that the purpose of reregistration is to assure that older chemicals are used safely. Thus, throughout our work, EPA has focused on taking action to eliminate unacceptable risks as they are identified. Not only have all REDs contained risk reduction requirements, but EPA has taken interim risk reduction measures affecting hundreds of pesticides, and has removed many uses or entire pesticides from the market based on new evidence of health and environmental risks. For example, EPA's current list of pesticides developed for the international Prior Informed Consent (PIC) program, lists 53 pesticides that are banned for all or virtually all uses. Examples of actions in recent years to deal with high risk pesticides and uses include:

- 80 uses of ethyl parathion voluntarily removed;
- Eliminating over 95% of granular carbofuran uses;
- Canceling all home use products containing metam sodium;
- Eliminating the use of aldicarb on bananas;
- Removing mercury compounds from paint;
- Imposing stringent new precautions on the fumigant methyl bromide for structural fumigation uses;
- Comprehensive risk reduction program for 2,4-D, primarily for worker protection;
- Moving quickly to obtain voluntary cancellation of the insect repellents "6-12" and "R-11," after receiving studies indicating potential adverse effects;
- Elimination of a number of EBDC fungicide uses, while retaining uses with negligible risks after considering any new use restrictions; and
- Reduction of risks to birds from the use of 14 granular pesticides through significant use amendments and label changes.

Accelerating the Pace of Reregistration. While there are tangible and important accomplishments from the last five years of effort, I think everyone believes EPA must step up the pace. Fortunately, there are several reasons to

expect that that will happen. First, EPA has almost completed calling in the data on active ingredients needed to complete reregistration. EPA has issued almost 315 comprehensive Data Call-Ins (DCIs) identifying remaining data gaps, and will complete nearly all of the remaining DCIs this calendar year. We expect to receive 20,000-30,000 studies on active ingredients over the course of the reregistration program. This effort to prime the pipeline for future REDs accounts for 20% of reregistration resources spent over the last five years, but last year accounted for 40% of science resources. After FY '93, these resources can be devoted to RED production and reducing the backlog of unreviewed studies.

Second, EPA has reviewed a substantial portion of in-house studies, particularly the most critical studies. Excluding product chemistry studies, OPP has reviewed about two-thirds of the almost 8,700 studies submitted for the List A pesticides. List A chemicals include most of the pesticides which have agricultural uses. For the List A public-health sensitive chronic feeding, carcinogenicity, reproductive and developmental studies, OPP has reviewed 75% of the over 750 studies received. Submitted studies showing potential adverse effects must now be clearly identified by registrants, and these studies are given priority review in OPP. Our adverse effects team is keeping abreast of new submissions, so that any problem chemicals are found well before the RED is issued.

Finally, EPA has made important management improvements to the reregistration process -- particularly with respect to study rejection rates and waiver and protocol decisions. These changes should assure smooth, efficient decision-making in the future. EPA has discovered that the submission of studies deemed unacceptable when reviewed by EPA scientists is the most significant factor delaying the Agency's RED decisions. Conducting replacement studies can add several years to the reregistration process. EPA's study of rejection rates,

with the cooperation and active involvement of pesticide industry scientists, is an intensive effort to analyze the reasons for rejected studies, and to address the underlying problems causing rejection. The assessment should be completed this summer. In addition, registrants often ask for waivers from data requirements. As shown in Charts 4 and 5, we have placed a major emphasis on reducing waiver backlogs so that multi-year studies can begin. In addition, we are expediting review and approval of registrants' study protocols, ensuring that the study design is acceptable before expensive studies begin.

Reregistration Schedule and Funding Thus, while I have considerable optimism about the pace of future reregistration decisions, it has been clear for some time that EPA will not meet the statutory goal of making all RED decisions by 1997, a point that was reported to you in October 1991. Taking into account present levels of funding for reregistration, we have developed our best schedule for reregistration decisions (REDs), shown in Chart 6. As indicated by the table, we expect to issue REDs for about 55% of reregistration cases by FY '97, although REDs would cover 86% of List A cases which includes most of the high volume food use chemicals. The remaining REDs will be issued between 1997 and 2004.

There are several reasons why EPA is not meeting the 1997 deadline. First, the statutory deadlines for issuing initial Data Call-Ins were unrealistically short. To decide what studies needed to be performed, EPA had to review in some depth the existing data bases on approximately 500 reregistration cases in four years. As noted above, we will be completing that step in five years. Second, building the infrastructure -- initially hiring and training 250 new staff, designing and implementing new computer systems, *etc.* -- has proven far more demanding than expected. Third, the 1997 goal completely failed to take into account the

possibility that registrants will need to perform higher tiered tests or repeat studies. We expect such studies will be required in many cases.

To appreciate the resources needed for reregistration, consider what Congress has asked of the Agency. In simple terms, the 1988 FIFRA amendments directed EPA to complete reregistration in 9 years, which EPA had earlier projected would take 35 to 40 years at then current funding levels. To achieve this 4 fold acceleration, Congress doubled EPA's resources by imposing on the pesticide industry both a one-time reregistration fee on active ingredients and an annual product maintenance fee. Unfortunately due to the statutory caps on payments by individual registrants and the high dropout rate for products, the revenues from maintenance fees fell \$13 million short of expectations over the last five years. Further, reregistration fees for active ingredients also came in at the low end of projections. As a result, reregistration has not had as much support as we expected. Moreover, and not surprisingly, reregistration is somewhat more costly than originally projected.

Although our 1988 plans assumed a gradual decline in workyears through 1997, the resource shortfall is aggravating this trend, just as our RED production schedule increases (refer to Chart 7). It is critical to maintain sufficient staffing to eliminate the unreviewed study backlog, since we expect a significant percentage will be rejected and need to be repeated.

IV. EMERGING CONCERNS

Three areas stand out as important for the future of pesticide regulation: (1) the National Academy of Science (NAS) report on the impact of pesticide residues in the diet of infants and children; (2) EPA's implementation of the Ninth Circuit's decision interpreting the Delaney clause; and (3) the plight of growers dependent on a dwindling selection of minor use pesticides.

NAS Children's Study. On June 29, the NAS is expected to issue its long-awaited report on their study of the impacts of pesticides in the diets of infants and children. Although the Academy is not discussing the findings or recommendations prior to the release, I expect the report to be a thorough and thoughtful examination of the nature of scientific knowledge in this very important area. We know already that there are areas where improvements are needed -- food consumption data; expanded, state-of-the-art testing for toxicological effects, for example -- and we look forward to the Academy's recommendations and plan to move ahead quickly to develop approaches that best implement the improvements necessary to safeguard our children's health.

Interpreting the Delaney Clause. EPA is taking action in accordance with the Ninth Circuit U.S. Court of Appeals' interpretation of the Delaney clause. As you will recall, the Natural Resources Defense Council (NRDC), the State of California, and others petitioned EPA to revoke 14 existing FFDCA sec. 409 tolerances for 7 chemicals in 1989. In response, after reviewing the petition, EPA proposed to revoke some and, based on the conclusion that some posed only a trivial, or *de minimis* risk, to retain others. The petitioner challenged EPA's action in the Ninth Circuit, which eventually ruled in their favor, concluding that the Delaney clause of section 409 had to be interpreted literally.

EPA has already taken several actions, and numerous activities are underway, to implement the court's interpretation of the Delaney Clause which I will briefly describe.

Release of list of potentially affected chemicals and crops. On February 2, 1993, EPA made public a list of pesticides and crops, in addition to those in the NRDC petition, that might potentially be affected by the court decision. The list was divided into two parts; one list identified chemicals that currently had FFDCA

sec. 409 tolerances and that probably would meet the Delaney clause "induce cancer" standard because EPA had classified them in Group A, B, or C under the EPA guidelines for evaluating potential human carcinogenicity. The second list identified pesticides that appeared to meet the Delaney clause "induce cancer" standard and for which EPA had data showing that the residue of the chemical would concentrate during processing of one or more raw agricultural commodity (RAC), but for which no FFDCA sec. 409 tolerances had been established. The lists included a total of 32 different active ingredients and over 80 different chemical/crop combinations.

NFPA Petition and EPA's Request for Comment. There are a number of significant legal and policy issues EPA must answer as it moves to implement the Ninth Circuit's interpretation. The National Food Processors Association (NFPA) filed a petition challenging certain of EPA's existing policies. EPA published a notice in the *Federal Register* on February 5, 1993, announcing receipt of the petition and requesting comment on these issues, as well as several additional issues. The issues include:

- whether to modify EPA's "coordination policy," which provides that EPA will refuse to issue a new sec. 408 tolerance (or will revoke an existing sec. 408 tolerance) for any pesticide that is barred from obtaining a needed sec. 409 food additive regulation, [issue raised by NFPA];
- whether to modify EPA's "concentration policy," which provides that a sec. 409 tolerance is needed whenever the residues in a RAC concentrate during processing of the RAC into a processed form, [issue raised by NFPA];
- whether to modify EPA's policy of denying registration for pesticide uses (or canceling existing registrations) when the use needs, but cannot obtain, either a sec. 408 or sec. 409 tolerance;
- whether to modify EPA's and FDA's current interpretation of the phrase "ready to eat" in the "flow through provision" of sec. 402, which provides that processed foods are not adulterated under FFDCA if, when ready to eat,

they contain residues below the section 408 tolerance for the RAC from which the processed food was made;

- how to interpret the "DES proviso" in section 409 which creates an exception to the Delaney clause for food additives that are found only in animal feed, that do not harm the animal, and that are not found in human food produced from such animals, e.g., meat, milk, eggs;
- whether the court decision affects the "constituents policy," which provides that the Delaney clause does not apply to a substance which contains an impurity or contaminant that induces cancer, if the substance itself does not induce cancer;
- how the court decision may affect EPA's approach to granting emergency exemptions for use of unregistered pesticides;
- whether EPA should modify its practices in determining the appropriate level at which to set section 408 tolerances on raw commodities, for example by excluding from consideration high-end residue values obtained in field trials conducted under the highest usage conditions permitted by the pesticide label; and
- what are the impacts on agriculture, the food industry, and consumers of pursuing different policy choices identified in the FR notice.

Delaney and Emergency Exemptions. Most recently, on Friday, May 7, EPA, USDA, and FDA, jointly issued a statement of policy on the way in which EPA will review and approve requests for emergency exemption under FIFRA sec. 18 in light of the Ninth Circuit's decision. According to this policy, EPA revoked 5 previously granted emergency exemptions and denied another 16. Although EPA concluded that there were no unreasonable risks to public health from the pesticide uses involved, the Agency thought that it had little choice but follow the court's interpretation.

The policy states that EPA will not issue an emergency exemption for a pesticide use which meets the following two criteria: (1) the pesticide appears to

meet the "induce cancer" standard of the Delaney clause, and (2) the pesticide residue will concentrate when the raw agricultural commodity is converted into a processed food form. In all likelihood under current policies, such a pesticide use would need, but could not obtain, an FFDCA sec. 409 tolerance, because of the Delaney clause.

EPA concluded that, under current policies linking registrations and tolerances, EPA could not find that there was progress toward registration, one of the criteria for a repeat emergency exemption to be issued. Further, FDA concluded that it could not continue to exercise its enforcement discretion to allow food containing residues resulting from use of such pesticides under emergency exemptions. FDA further announced that it would not seize food containing residues from treatments that occurred under FIFRA sec. 18 exemptions prior to the announcement of this policy. Rather, such food would still be allowed to pass through the chain of commerce, as long as the residues were below the expected levels identified by EPA.

NRDC Petition Chemicals. EPA is about to issue a *Federal Register* notice with respect to the four chemicals and seven tolerances that were named in the court's decision.

For the 3 chemicals and 7 tolerances addressed by the petition, but not involved in the litigation, EPA has taken, or plans, the following actions: EPA has revoked the section 409 tolerances for chlordimeform on dried prunes and DDVP on dried figs. EPA has proposed to revoke the sec. 409 tolerances for dicofol on dried tea and DDVP on packaged and bagged nonperishable foods. EPA plans to issue final notices with respect to dicofol and DDVP this month or next. Since the DDVP section 409 tolerance for bagged and packaged foods represents use of the chemical directly on processed foods, there is no corresponding section 408

tolerance. Accordingly, EPA intends to issue a notice of intent to cancel, removing a number of uses from DDVP labels.

The situation with regard to mancozeb on bran of oats, barley, and rye is more complicated. EPA had published a proposal to revoke these sec. 409 tolerances, but subsequently withdrew the proposal after concluding that the risks were trivial. Recently, the Mancozeb Task Force, a group of chemical companies supporting the continuation of registrations and tolerances for mancozeb, submitted a petition arguing that the sec. 409 tolerances should be revoked because mancozeb residues in oats, barley, and rye do not concentrate when these raw commodities are processed into bran.

EPA has recently published a notice in the *Federal Register* announcing receipt of the petition and inviting public comment. EPA intends to issue either a new proposal to revoke these sec. 409 tolerances because they cannot remain in effect under the court's interpretation of the Delaney clause, or a final rule granting the petition if the Agency finds, in light of public comment and other evidence, the grounds presented in the petition are valid. If EPA makes that finding, no uses will be affected. This action is also projected to be completed in the next two months.

Other Future Actions. By late fall, we intend to issue a proposal on how EPA will deal with the 32 pesticides potentially affected by the court decision (i.e., whether we will revoke food additive regulations and tolerances, and possibly cancel registrations) under policies addressed in the February 5 *Federal Register* notice. Also late this summer, we are planning a proposed rule that would systematically classify food forms as "raw agricultural commodities" subject to section 408 of the FFDCA or as "processed food" potentially subject to section 409. Collectively, these actions demonstrate EPA's strong commitment to complying with the rule of law as defined by the Ninth Circuit.

Delaney and Legislation. While EPA is moving to implement the Ninth Circuit's interpretation, we do not consider that to be good public policy. As the court said, after noting that more than one scientific authority has criticized the statutory scheme established by the Delaney clause, "Revising the existing statutory scheme, however, is neither [the court's] function nor the function of the EPA.... If there is to be a change, it is for Congress to direct."

Accordingly, as part of its announcement of a new policy on emergency exemptions, the Administration stated that it will seek legislation to change current law governing pesticides and food safety. EPA Administrator Browner said, "The Clinton Administration will work with Congress and other interested parties to develop a proposal. The proposal must reflect sound public policy and science and strengthen the current law for regulating pesticides and their residues. Most important, any legislative package must assure the overall safety of the food supply."

The Administration has set up a work group including USDA, FDA, EPA, and the White House Domestic Policy Council to develop the Administration proposal. Although we have set no deadline for public presentation of the proposal, the work group will be moving ahead quickly. The Administration is aware that several bills to amend the statutes regulating pesticides have been introduced in this Congress, including H. R. 1627 (Food Quality Protection Act of 1993), sponsored by Reps. Lehman, Bliley, and Rowland; and S. 331/H. R. 874 (Pesticide Food Safety Act of 1993), sponsored by Sen. Kennedy and Rep. Waxman. The Administration has not developed a position on these bills, but will be considering them carefully as we develop our positions.

Minor Use Pesticide Policy. As you know, minor use pesticides are uses of pesticides for which the potential profit for a registrant does not justify the cost of

registration or reregistration. The crops on which these pesticides are used, however, are far from being minor; they include all fruits, vegetables, nuts, as well as some public health, field crops, and livestock uses. The pressures on pesticides for minor use intensified as a result of the 1988 FIFRA amendments.

Reregistration data requirements are leading registrants not to support many minor uses in the reregistration process. Minor food uses most often lack residue chemistry data, since the major food uses for a pesticide normally trigger the more expensive and time-consuming core hazard characterization data. Lack of support by the registrant results in voluntary use deletions or even loss of entire pesticides. Other economic factors, such as limited markets, mandatory fees, and, in some cases, liability concerns are considered by registrants in making decisions whether or not to support pesticides in the reregistration process. For the same reasons, registrants may choose not to seek approval of minor uses in applications for new pesticides that might replace disappearing uses.

The full scope of the problem is not yet known. About 4,000 tolerances are currently established for minor food crops. Based on national surveys and input from workshops, the U.S. Department of Agriculture (USDA)/ State Interregional Research Project No. 4 (IR-4) program estimated in 1990 that about 1,000 tolerances that are important for agricultural minor uses will not be supported by registrants with required residue data. IR-4 will be updating its survey on supported/unsupported uses this summer.

In many cases, IR-4 is developing data for uses not being supported by the registrant. Steady increases in funding have facilitated this effort, and the \$12.5 million requested for IR-4 in USDA's FY '94 budget, double the 1993 level, is close to the identified need level of \$14 million annually. EPA supports increased funding for IR-4 as the most effective way to ensure long-term retention of

important minor uses without sacrificing timely health and safety data development and reviews.

EPA is making many efforts within our current authorities to assist in retaining minor uses. We are helping retain important minor uses by: (1) working closely with USDA and IR-4; (2) granting requested low volume/minor use data waivers whenever possible; (3) moving to revise our crop grouping regulation; (4) encouraging third party registrations; (5) reducing or waiving fees and expediting processing; and (6) encouraging agricultural chemical users to work with the pesticide industry.

Regarding possible minor use legislative changes, you are aware that the broad-based Minor Crop Farmers Alliance (MCFA) developed minor use initiatives, and that Congressman de la Garza and Senator Inouye have introduced minor use bills. The intent of the legislative language is to facilitate retention of current minor uses and the addition of new minor uses. The legislation would define minor uses, encourage data waivers and conditional registrations, extend the period of exclusive data use, extend the time allowed for development of minor use data, provide for temporary extension of unsupported minor uses, allow easier revival of canceled chemicals, and require expedited approval of certain new minor use requests. While the current Administration has not yet taken a position on these bills, EPA does recognize the serious nature of the problems facing minor use pesticides.

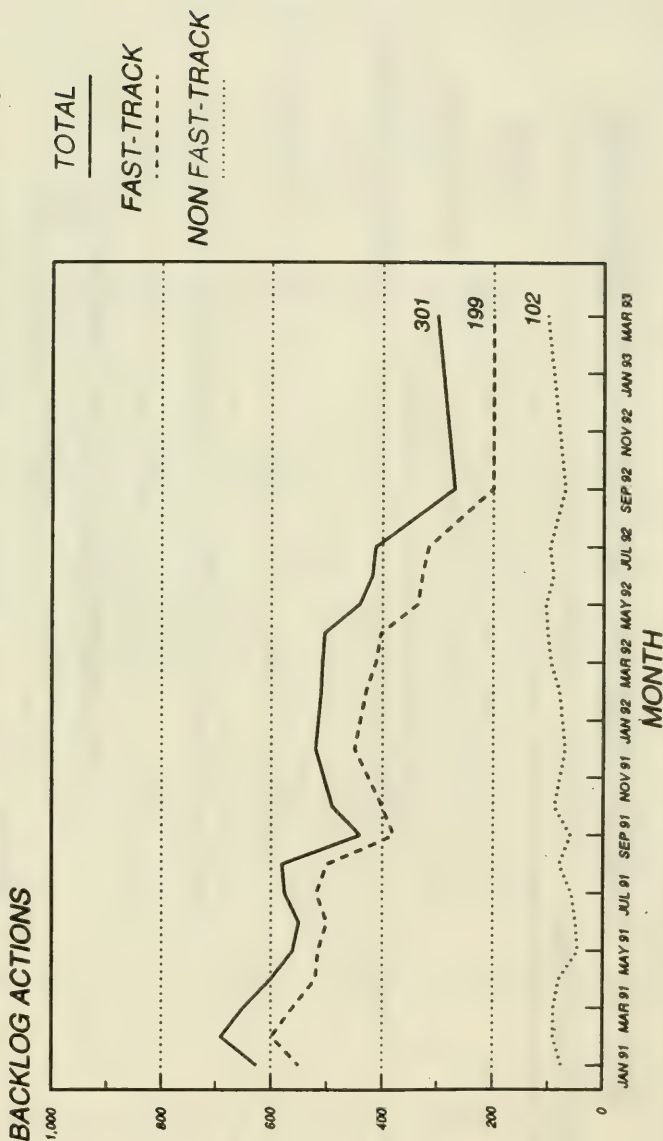
In closing, I want to emphasize that much progress has been made on reshaping the program to deal with the challenges created by FIFRA '88 and changes in agriculture and public concern. Nonetheless, much remains to be done.

(Attachments follow:)

Chart 1

OLD CHEMICAL BACKLOGS

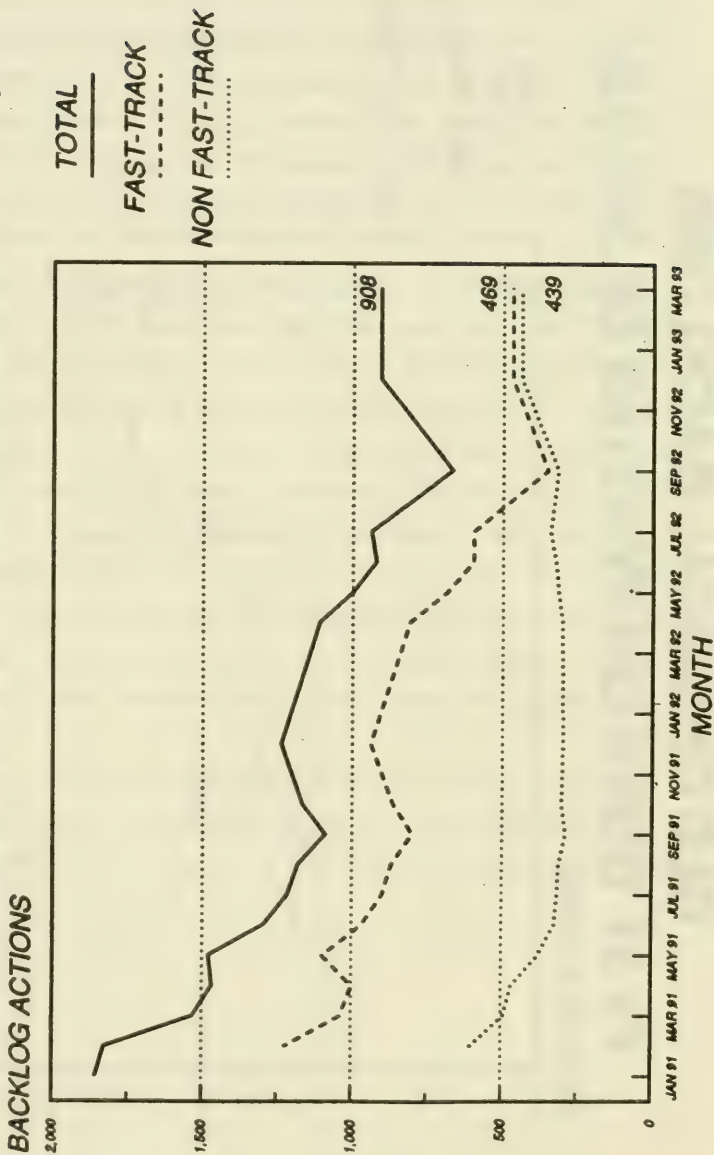
FY 91 THROUGH FY 93 (AS OF 3/31/93)



Data was not collected during the 1st Quarter of FY 93.

AMENDMENT BACKLOG

FY 91 THROUGH FY 93 (AS OF 3/31/93)





Office of Pesticide Programs

PRODUCT REREGISTRATION

- Approximately 20,000 products subject to reregistration
- Approximately 2,260 products associated with the 31 REDs that have been issued
 - 14-24 month lag from RED issuance to product reregistration
- Actions as of February 1993
 - 33 products reregistered
 - 288 products voluntarily cancelled
 - 2 amendments (multiple AIs)
 - 298 products sent to OCM for suspension
- Issues
 - significant numbers of deficient applications have been submitted requiring multiple cycles and causing delays.

Chart 4

Office of Pesticide Programs



LIST A
Pending and Completed Waivers

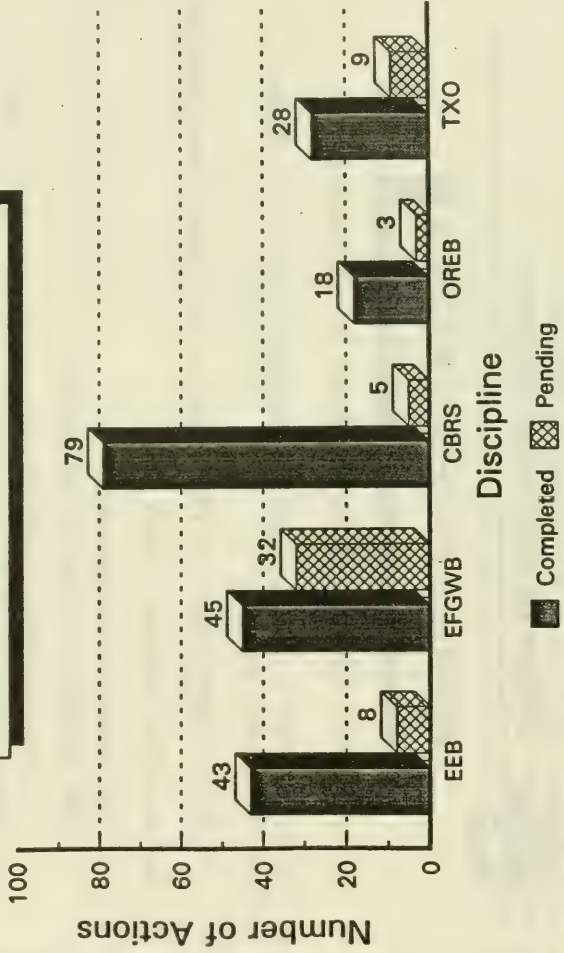
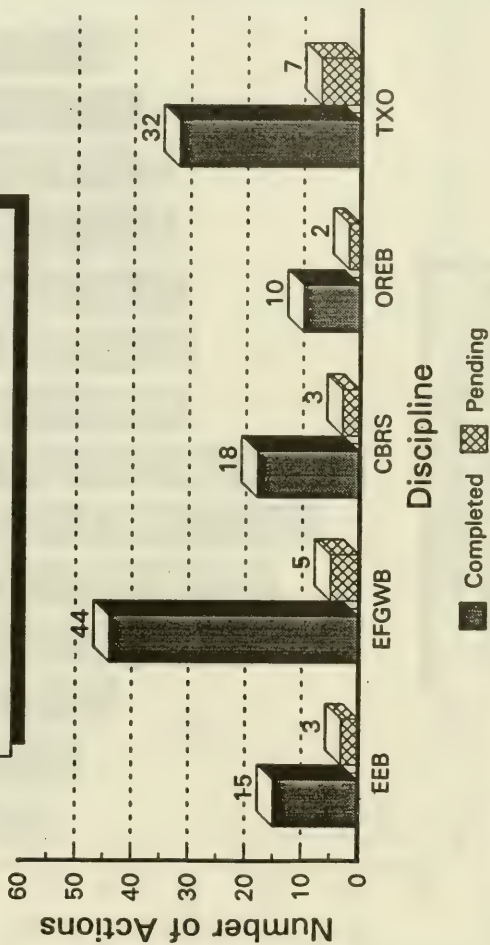


Chart 5



Office of Pesticide Programs

LIST B, C, D Pending and Completed Waivers



* Additionally, hundreds of other waivers for List B, C, D chemicals addressed through Phase 2 and 4 review, outside of Graybeard Workshop.

Chart 6

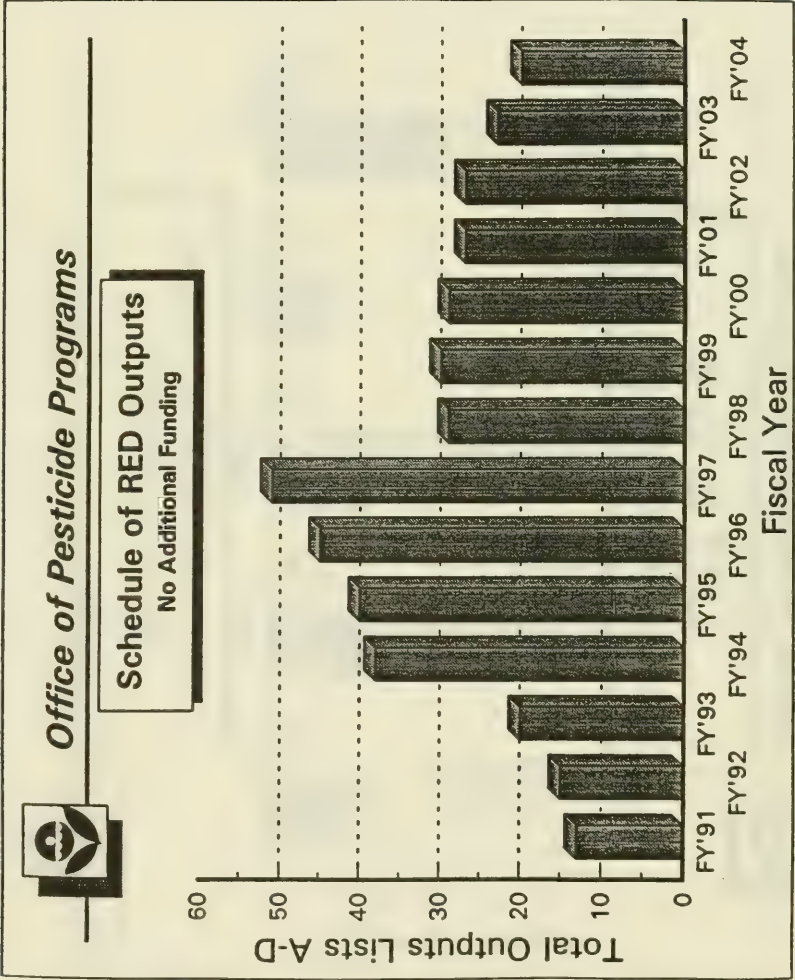
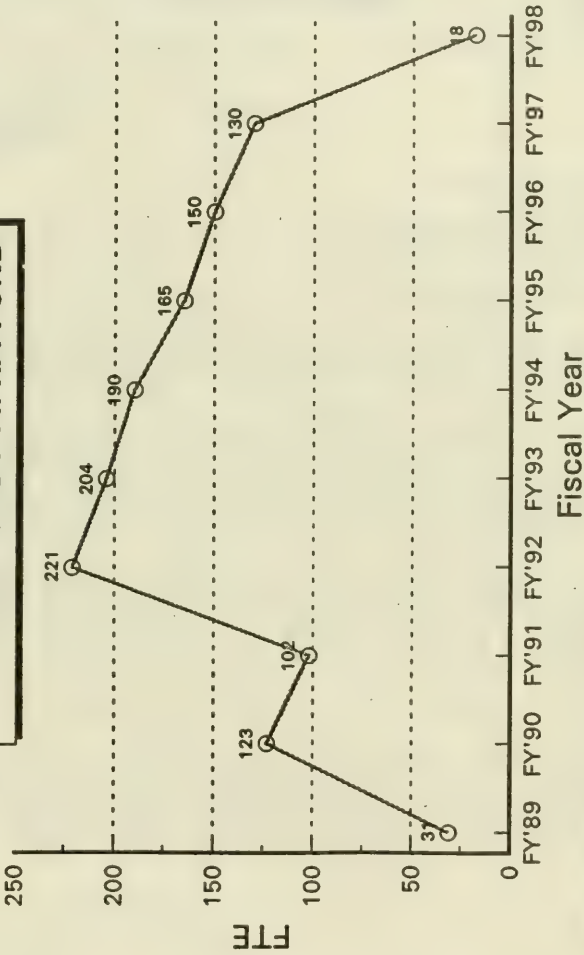


Chart 7

Office of Pesticide Programs

FTE COVERED BY FIFRA FUND



Note: Decrease in FY'91 FIFRA FTE due to one-time increase in appropriated FTE



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

SEP 28 1993

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Honorable Pat Roberts
Ranking Member
Committee on Agriculture
House of Representatives
Washington, D.C. 20515

Dear Congressman Roberts:

We noted several questions or issues raised in your opening statement for the June 8, 1993 hearing that were not addressed in our testimony. The purpose of this letter is to respond to these questions.

First, you asked if EPA could provide an accounting of reregistration fees collected and how they have been used. In this context, you also asked if EPA has kept detailed records on the appropriations shortfalls that have contributed to these projections -- particularly with respect to the projections made during passage of the 1988 amendments to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA '88).

After the hearing, we provided to Committee staff the enclosed report on the amount of fees collected and on the use of these funds. We would be pleased to brief you or your staff on this report if you believe this would be helpful. Our information on the amount of fees collected is derived from records kept of daily receipts at the Agency's lockbox for fees, which serves to ensure that maintenance and reregistration fees are correctly identified and credited to our account.

The answer to your question about the role of appropriations in the funding shortfall is more complex. The Agency made projections of funds available and needed for reregistration at the time Congress was considering FIFRA '88, and has continued to update these projections since that time. The pre-FIFRA '88 and current projections for fiscal years (FYs) 1989 through 1997 are summarized on the next page.



Recycled/Recyclable
Printed with Soy/Canola Ink on paper that
contains at least 50% recycled fiber

REREGISTRATION FUNDING PROJECTIONS: FY 89 - FY 97
 (\$ in millions - rounded)

	<u>June 1987 Est.</u>	<u>Current Est.</u>
Appropriated Funds	110	169
Reregistration Fees	24 - 46	29
Maintenance Fees	104 - 126	115
Interest/Refunds/ Sequesters	--	3
Shortfall	--	20
	-----	-----
TOTAL	238 - 282	336

In the above projections, it is evident that the estimate for "Appropriated Funds" available for reregistration has grown significantly -- by \$59 million -- since the June 1987 estimate. This increased estimate in available appropriations reflects actual and projected appropriation increases for salary growth, as well as specific appropriations actions affecting the reregistration program. It is important to recognize that while the total appropriated funds have increased significantly, the amount of funds provided by industry have been at the low end of the estimated projections. Therefore, if one maintains the expectation of about a 50/50 government/industry sharing of the reregistration cost, the shortfall could be attributed to a lack of funds from the industry, not from the Congress.

OPP made the June 1987 estimate after reviewing a proposed FIFRA bill. No estimate was made at that time for other Agency costs. The analysis noted that the cost estimates were rough in nature and subject to substantial change, because the final legislation was not completed and the major changes to the reregistration process would require rapid implementation of a number of very complex activities for which there was little or no historical experience. The unfunded projection of \$20 million (5% of total costs) is remarkably small considering the inherent uncertainties in projecting costs for a program of uncertain scope.

If the unfunded shortfall is covered, we project that 63% (258) of the 407 reregistration cases would have a registration decision by FY 97, including 86% (131) of the 152 List A cases. The last reregistration case decision would be issued in 2001. The current unfunded estimate is dependent on pending budget requests and appropriations actions. Also, we are just beginning the most intensive stage of producing reregistration decisions, which may alter the cost projections somewhat.

Second, you asked about EPA's compliance with Section 1491(f) of the 1990 Farm Bill that states the "Secretary of Agriculture and Administrator of the [EPA], shall survey the records maintained under subsection (a) to develop and maintain a

data base that is sufficient to enable the Secretary and the Administrator to publish annual comprehensive reports concerning agricultural and non-agricultural pesticide use..." You also asked about the status of the record keeping "memorandum of understanding" between USDA and EPA called for in Section 1491(f).

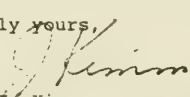
We are proceeding with plans to undertake this survey in FY 94. We regret that the survey could not be conducted in FY 93 due to reductions in appropriated funds available to OPP. The enclosed May 19, 1993 letter to Congressman de la Garza, a copy of which was forwarded to you, describes the major reduction in FY 93 OPP appropriations compared to the budget request. The purpose of the May 19 letter was to alert the Congress that the appropriations reduction prevented us from fulfilling the authorization requirement this year. Funding this new activity at a time of major across-the-board reductions would have had a devastating effect on other program activities in FY 93.

The Administrator recently made available to OPP \$0.5 million to initiate FY 94 survey work. In addition, we requested permission on July 22, 1993 from the Appropriations Committees to reprogram an additional \$0.9 million of expiring funds for this purpose. We believe that this total funding of \$1.4 million would permit a statistically valid national survey of the EPA portion, covering a sample of 4,000 certified commercial applicators using non-agricultural, restricted use pesticides. The field data collection is projected for January - March 1994, and the final report would be issued by September 1994.

We have worked with USDA on a Memorandum of Understanding (MOU) specifying our mutual roles in the recordkeeping survey, but have delayed signing it because of the FY 93 budget reductions. We expect to have the final MOU in place this year.

I hope this information is helpful. Please let me know if you have any questions.

Sincerely yours,


Victor J. Kimm
Acting Assistant Administrator

Enclosures

cc: Congressman E "Kika" de la Garza
Chairman, Committee on Agriculture

February 3, 1993

EPA'S USE OF REREGISTRATION RESOURCES -- FY 1989-1992

The Environmental Protection Agency (EPA) was mandated by Congress to regulate the use of pesticides and to balance the risks and benefits posed by pesticide use. The agency regulates the use of pesticides through its Office of Pesticide Programs (OPP), within the Office of Prevention, Pesticides and Toxic Substances (OPPTS). OPP is a matrix organization consisting of seven divisions and a staff office. Over the past four years, OPP has spent a total of \$136.2 million on the accelerated reregistration program. Attachment 1 shows a distribution by function of where the funds were used, and attachment 2 summarizes the accomplishments of the program through 1992. OPP uses both appropriated and revolving funds in accomplishing its mission.

Of the total funds spent on the pesticides reregistration program, \$69.6 million went for salaries and expenses to support in-house OPP staff. The reregistration process is part of the broader pesticide program mission to serve the nation by safeguarding public health and the environment from risks posed by pesticides. The regulation of pesticides comes under two statutes - the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA). FIFRA gives EPA the authority and responsibility for registering pesticides for specified uses and the reregistration of existing pesticides that were registered prior to November 1, 1984. Pesticide regulatory decisions are based primarily on EPA's evaluation of the test data provided by applicants.

The reregistration process is conducted through reviews of groupings of similar active ingredients called cases. There are five (5) major phases of reregistration:

- o Phase 1 - Listing of Active Ingredients. EPA had to publish lists of active ingredients and asked registrants whether they intended to seek reregistration. This was completed in 1989. 1153 active ingredients from 611 cases were initially listed as subject to reregistration.
- o Phase 2 - Declaration of Intent and Identification of Studies. Registrants had to notify EPA of their intent to reregister and to identify missing studies. This was completed in 1990.
- o Phase 3 - Summarization of Studies. Registrants had to submit required existing studies. This was completed in 1991.
- o Phase 4 - EPA Review and Data Call-Ins (DCIs). EPA has to review the studies, identify and "call-in" missing studies by issuing a DCI. A "DCI" is a request to a pesticide registrant for scientific data to assist the Agency in determining the pesticide's eligibility for reregistration. 283 DCIs were issued through 1992.

- o Phase 5 - Reregistration Decisions. EPA must review all studies and issues a Reregistration Eligibility Document (RED) for the active ingredient(s). A "RED" is a determination by the Agency whether products containing a pesticide active ingredient are eligible for reregistration. The registrant complies with the RED by submitting product specific data and new labels. On the basis of its review, EPA reregisters or cancels the product. Pesticide products are reregistered, based on a RED eligibility determination, a process designed to ensure that it has met all label requirements. This normally takes 14 to 20 months after issuance of the RED. As of June, 1992, for List A, 6587 studies were reviewed out of 11,700 received. We expect to receive another 1200 studies. Through 1992, OPP issued 28 REDs, reregistered 41 products, canceled 165 products, and suspended 308 for not responding to REDs.

\$16.8 million in extramural funds were paid to contractors to review scientific studies submitted by registrants in support of pesticide registrations. The types of studies examined range from minor product chemistry data reviews to complex multi-year oncological studies. The results of these studies and subsequent reviews form the basis for a set of actions required in the REDs. These required actions impact one or more of the three risk reduction measures (dietary exposure, non-dietary exposure, and environmental fate and ecological effects).

In order to process all the data required by the accelerated reregistration effort, \$14.9 million were spent on a local area network, basic ADP operations, and numerous specialized information systems (see Attachment 3). These systems provide support for the following reregistration phases and functions: List A Inventory; List A DCIs; Phase II -- Lists B, C, and D; Phase III -- Lists B, C, and D; Phase IV -- Lists B, C, and D; Reregistration and Maintenance Fees; On-going DCI Management; REDs; and Product-level Reregistration.

\$9.3 million in extramural funds were used in the following areas to supplement in-house reregistration staff: AARP Support; Special Review and Reregistration Division support; Communications/Outreach; Universities/IAGs/Research Groups for determining chronic effects of pesticides, risk assessment methodologies, assessment of toxicological data, and other research functions; word processing support; and other pesticide reregistration support projects.

From 1989-1992, \$9.0 million were used by the following other Agency offices in support of pesticide reregistration (see Attachment 4): Office of Compliance Monitoring (\$5.7M), Office of Administration and Resources Management (\$1.6M), Office of Water (\$1.0M), Office of Enforcement (\$0.5M), and Office of General Counsel (\$0.1M). Totals do not add due to rounding. Starting in 1993, OPP will be the only office using revolving funds.

Standard overhead expenses totaling \$6.4 million went to the Office of Administration and Resources Management for agency facilities support.

\$7.3 million were spent to purchase personal computers (PCs) and related software; and to install, upgrade, and maintain Local Area Network (LAN) systems (see Attachment 4). The number of personal computers has grown in OPP from 125 PCs for 570 staff in 1988 to 805 PCs for 803 staff in 1992.

\$1.6 million were used for space moves (\$0.3 million) and purchasing furniture and other equipment (\$1.3 million) needed to support additional staff hired to perform reregistration functions.

\$1.3 million in extramural funds were used to support the processing of fast track amendments and old chemical reviews. The funds were used to hire AARP employees through the Senior Environmental Employees (SEE) program. These AARP employees are located in OPP's Registration Division and perform front end processing and other functions in support of fast track registration work. Through 1992, OPP completed 3568 fast track old chemical registrations and 10,466 amended registration reviews.

02/03/93

EPA'S USE OF REREGISTRATION RESOURCES -- FY 1989-1992
(\$millions)

Function	Appropriated Funds	Revolving Funds	Total
=====			
OPP Personnel Costs	46.0	23.6	69.6
Science Reviews/DCIs	7.4	9.4	16.8
Information Mgmt Sys	8.0	6.9	14.9
Other OPP Extramural	2.1	7.2	9.3
Other Offices' (non-OPP)	0.0	9.0	9.0
Agency Facilities Support	0.0	6.4	6.4
Local Area Network	0.3	5.0	5.3
Personal Computers	0.6	1.4	2.0
Space Moves and Furniture	0.0	1.6	1.6
Fast Track Processing (E/M)	0.3	1.0	1.3
Total	64.7	71.5	136.2
=====			

Summary of Accomplishments under FIFRA '88

- 1) Completed 283 Comprehensive Data Requirements in Data Call-Ins (DCIs),
- 2) Completed 28 Reregistration Eligibility Documents (REDs) or "other appropriate regulatory action,"
- 3) Completed 206 Product Specific Reregistration actions,
- 4) Completed 3,568 "Fast-track" Old Chemicals, and
- 5) Completed 10,466 "Fast-track" Amended Registrations.

ARTS/SMART	ALISS	DCI	LUIS	PPIS/REFS	PRES	PIRITS	POMIS	Phase III Inprocessing Systems	Fee
System Functions: <ul style="list-style-type: none"> • Capture & Archive of Phase II Responses • Manage Worker Dispatches, Time Extensions, Etc. • Capture Science Decisions • Generate Phase II Materials 	<ul style="list-style-type: none"> • A-Lat History • Science Decisions • ID Data Goals, Overview, Etc. 	<ul style="list-style-type: none"> • ID Data Requirements • ID Components & Products for Each AI • Generate DCI Forms • Capture ID-Data Requirements • Track Data Packages by/From Science (with PIRITS) • Candidate All DCIs for All AIs • Track Submissions (with PRES) • Track Workers, Time Extensions, Etc. • Track Study Dates, Receipts 	<ul style="list-style-type: none"> • Capture Labeling Information, Peer, Acceptation Notes, Use Restrictions • Aggregate Analysis by AI • Science Decisions • Record Rejection Decisions on Issues (RED) • Identify Product Handling Changes 	<ul style="list-style-type: none"> • Capture Labeling Information, Peer, Acceptation Notes, Use Restrictions • Capture & Monitor Vocabularies, Company Norms & Activities, General Product Information • Generate Mailing Envelopes • Analysis of Impact of Disposal 	<ul style="list-style-type: none"> • Support OC/MOPP in Managing Submission Information • Generate Notice to Submit (NOTS) • Process Submissions 	<ul style="list-style-type: none"> • Manage Information on All Types of Regulatory Action/Submissions • From ID/2000 by/From Science • Record Science Results • ID to/from Regulatory • Identify Pending/Over-due Action/Submissions 	<ul style="list-style-type: none"> • Manage Information on All Studies/Summaries/Reports • Bibliographic • Science Results • ID to/from Regulatory • Identify Pending/Over-due Action/Submissions 	<ul style="list-style-type: none"> • Capture Phase II Responses • Microfilm Studies • Summaries and Unpublished Studies • Track Payments • ID Non-Respondents 	<ul style="list-style-type: none"> • Manual Share Analysis • Computerized • In Use on Standalone PCs
System Functions: <ul style="list-style-type: none"> • In Use on LAN • Just Modified to Accept Phase II Information 	<ul style="list-style-type: none"> • In Use on LAN • 200 hrs of four Bugs 	<ul style="list-style-type: none"> • DCI Generation in Use Since LAN Version to be Completed 1/90 • ID-Data Response Module to be Completed 1/90 • DCI Management Module to be Completed 12/90 	<ul style="list-style-type: none"> • Lat II Data Entry Almost Complete • Field Reports Being Generated • Discharge Conversion Module to be Completed 1/90 • Reports Need Refinement • No On-line Question Yet 	<ul style="list-style-type: none"> • In Use on LAN • No Automatic Loading of Information From Other Systems • Data in RESS on LAN & State • Not Integrated With Other Systems 	<ul style="list-style-type: none"> • In Use on LAN • No Guideline Level Loading • Not Integrated With Other Systems 	<ul style="list-style-type: none"> • In Use on LAN • No Guideline Level Loading • Not Integrated With Other Systems 	<ul style="list-style-type: none"> • In Use on Mainframe 	<ul style="list-style-type: none"> • In Use on Standalone PCs 	<ul style="list-style-type: none"> • In Use on Standalone PCs
Phase: <ul style="list-style-type: none"> • Maintenance Mode • Complete Data Capture for All Units 	<ul style="list-style-type: none"> • Maintenance Mode 	<ul style="list-style-type: none"> • LAN Version of DCI Generation to be Completed 1/90 • ID-Data Response Module to be Completed 1/90 • DCI Management Module to be Completed 12/90 	<ul style="list-style-type: none"> • Complete Discharge Conversion 1/90 • Beta Reports • Complete Data Conversion to be Completed 1/90 • A-D in C-91 	<ul style="list-style-type: none"> • Complete ADAS Conversion in FY91 • Integrate with LUIS on the LAN • Maintenance of Integrated System on the LAN in FY91 	<ul style="list-style-type: none"> • Integrate with ADAS/ALISS/DCI PIRITS/REFS • Impact Analysis of Disposal 	<ul style="list-style-type: none"> • Add Guideline Level Loading • Integrate With Other Systems on the LAN • Add I-Editor, Writing Support • Incorporate Science Branch Systems 	<ul style="list-style-type: none"> • Maintenance Mode 	<ul style="list-style-type: none"> • Complete Inprocessing Using LUIS & C.D. in FY91 • Process FY91 Maintenance Fee Cycle 	<ul style="list-style-type: none"> • Complete Re-generation of Disposal in FY91 • Process FY91 Maintenance Fee Cycle

BREAKOUT OF OTHER OFFICES USE OF REREGISTRATION RESOURCES
(\$millions)

1.	OCM --	\$5.7 (personnel costs: \$4.0; contracts: \$1.7)
2.	* OARM --	\$1.6 (personnel costs: \$1.6)
3.	OW --	\$1.0 (personnel costs: \$0.3; contracts: \$0.7)
4.	OE --	\$0.5 (personnel costs: \$0.5)
5.	OGC --	\$0.1 (personnel costs: \$0.1)

Total		\$9.0 (personnel costs: \$6.6; contracts: \$2.4)
-------	--	--

* (additional \$6.3 went to facilities support)

Note: Total does not add due to rounding.

MAY 19 1993

Honorable E (Kika) de la Garza
Chairman, Committee on Agriculture
United States House of Representatives
Washington, DC 20515-4605

Dear Mr. Chairman:

This is to inform you of a difficult situation we are facing this year. The 1990 Farm Bill requires that all certified applicators of restricted use pesticides (RUP) begin keeping records of their pesticides usage. The bill also requires that the United States Department of Agriculture (USDA) and the Environmental Protection Agency (EPA) survey the records of certified applicators and prepare an annual comprehensive report for Congress on pesticide usage. EPA was to conduct the non-agricultural portion of these surveys.

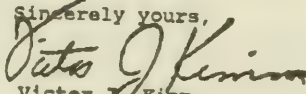
Toward this end, in Fiscal Year 1992, EPA laid the groundwork in preparation for a survey of the non-agricultural certified applicators. Specifically, we developed an Information Collection Request and forwarded it to the Office of Management and Budget (OMB) for approval under the Paperwork Reduction Act. We prepared a questionnaire, completed a preliminary test, constructed the sampling frame, and were ready to select a sample.

Due to recent reductions in our Fiscal Year 1993 budget, however, we are not in a position to conduct even a limited sampling survey of certified applicators in 1993. This year's budget constraints and decisions have adversely affected every aspect of the pesticide programs, including the National Pesticides Telecommunications Network, certification and training, reregistration, registration, and information management.

Therefore, we will not be conducting the first annual survey, during this fiscal year. Without the data from the planned survey, the Agency is unable to prepare a comprehensive report of pesticide usage as required by the 1990 Farm Bill.

I hope you will understand the difficult situation which has led to this and other program cut-backs. If you have any questions, or wish to discuss this further, please let me know.

Sincerely yours,

A handwritten signature in dark ink, appearing to read "Victor J. Kimm". The signature is fluid and cursive, with the first name "Victor" being more prominent.

Victor J. Kimm
Acting Assistant Administrator

cc: Craig Reed - USDA
Sam Rives - USDA

STATEMENT
on
THE FEDERAL INSECTICIDE, FUNGICIDE AND RODENTICIDE ACT
AND RELATED ISSUES
for submission to the
HOUSE COMMITTEE ON AGRICULTURE
SUBCOMMITTEE ON DEPARTMENT OPERATIONS AND NUTRITION
for the
U.S. CHAMBER OF COMMERCE
by
Steven Averbach*
June 23, 1993

The U.S. Chamber of Commerce Federation of local and state chambers of commerce, businesses, and associations has identified food safety as a policy priority of the National Business Agenda. The Chamber is the only business federation representing all segments of the food chain, including agrichemical manufacturers, growers, processors, and retailers. Because of the importance of affordable and readily available pesticide products to all links in the food chain, we appreciate this opportunity to comment on federal pesticide policy and related issues as the Subcommittee reviews and reauthorizes the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

The Chamber commends the Subcommittee for its commitment to deal with this complex and controversial issue, and we are confident that your leadership will result in a federal pesticide policy that takes into account the needs of the food industry, but has as its primary objective the health and safety of consumers.

Modern agriculture requires the use of crop protection chemicals to control weeds, insects, and other pests that threaten the nation's and the world's food supplies. Federal regulation of chemical and biological pesticide products is necessary to protect the environment and ensure public health and safety. Moreover, credible, scientifically-based regulation is essential to maintain public confidence in the safety of the food supply. These laws and regulations should also encourage innovation and the development of new, safe, and effective pesticides.

Regulatory decision-making should be timely, cost-effective, and based on the best available toxicological data, subject, when appropriate, to independent scientific peer review. This regulatory process should involve not only the detection and assessment of risks, but also their management within the total context of important social and economic benefits.

*Steven Averbach is Analyst, Food and Agriculture Policy

We would like to comment on specific FIFRA and pesticide policy issues.

REGISTRATION

The pesticide industry spends roughly \$800 million per year on new product research and development. A significant portion of that investment is devoted to the development of safer pesticides. Yet, the registration process — in terms of time and money — continues to be a disincentive for new product development. The Chamber supports streamlining the registration process in order to bring new and improved pesticide products to market in a more timely and cost-effective manner.

CANCELLATION

Pesticides posing an unreasonable health risk should be removed as quickly as possible from the market. The current cancellation process is much too lengthy and only weakens public confidence in the regulatory system. The Chamber strongly supports streamlining the cancellation process to reduce the time necessary to remove high-risk products from the market. However, we cannot support any amendments to FIFRA that would eliminate manufacturers' due process in cancellation procedures.

AUTHORITY OF STATES

The potential chaos that would result if the nation's roughly 80,000 local and municipal governments were to adopt different pesticide use regulations greatly concerns the businesses that rely on safe and effective pesticide products. Yet, that possibility exists in light of the 1991 U.S. Supreme Court decision in *Wisconsin Public Intervenor v. Mortier*.

The Chamber believes that Congress must address this issue, as the Court suggested, in order to restore the federal-state collaboration that has been effective for pesticide use regulation. We support localities' right to petition their state governments to address and resolve any special local pesticide needs or problems.

Last year, the Chamber supported H.R. 3850, the Federal-State Pesticide Regulatory Partnership Act, which preempted townships, municipalities, and counties from issuing regulations inconsistent with federal and state regulations. The Subcommittee adopted H.R. 3850 as part of its FIFRA bill. We urge you to include a similar provision in a FIFRA mark-up.

MINOR USE PESTICIDES

According to U.S. Department of Agriculture, "minor" agricultural crops — including fruits, vegetables, and nuts — account for 40 percent of the nation's agricultural production.

The continuing loss of minor use pesticides poses a real and serious threat to growers' ability to produce these essential commodities. The fact that the minor use problem is an economic issue and not a health issue cannot be emphasized too strongly. Currently, growers are bearing the burden of this problem. In the long run, however, the consumer will bear the burden in the form of decreased availability of fresh fruits and vegetables, higher prices, and decreased health benefits.

The Chamber again commends USDA, EPA, the Inter-regional Research Project Number 4 (IR-4), and the agrichemical industry for their commitment to easing the minor use problem by alerting growers to cancellations and working with them to find alternative crop-protection measures. Yet, we recognize that a true remedy to the problem will result only through this Subcommittee's leadership. Chairman de la Garza's bill, *inter alia* H.R. 967, the Minor Crop Protection Assistance Act of 1993, would expedite the review of applications and provide an extension of minor-use registrations and data submission deadlines. The Chamber urges you to include H.R. 967 as part of a FIFRA mark-up.

PESTICIDE EXPORTS

Calls to limit pesticide exports are based on unfounded food safety concerns. The premise of the "circle of poison" is that harmful pesticides produced domestically, but not registered for use in the United States, make their way back into this country on imported foods. There is no evidence that this problem exists. Further, many pesticides do not have a U.S. registration because there is no domestic crop or pest use, or because of a manufacturer's decision not to support a registration.

The Chamber supports a prohibition on the export of a pesticide if it is banned in the U.S. *for human health reasons*. In addition, we support a prohibition on the export of pesticides that contain an active ingredient that is not registered in the United States unless it has a U.S. food tolerance or exemption, or unless the active ingredient is approved for use in at least one OECD country. The U.S. must work toward international harmonization of maximum residue limits and scientific testing standards.

THE DELANEY OPPORTUNITY

The single most important issue currently facing businesses in the food chain is the July, 1992 Ninth Circuit's *Les v. Reilly* decision upholding a strict interpretation of the Delaney clause of the Federal Food, Drug and Cosmetic Act (FFDCA). We recognize that primary jurisdiction over the FFDCA lies outside this subcommittee; however, we know that a meaningful resolution to the Delaney crisis will come forth only with significant input from you.

There are efforts to resolve through an "administrative fix" some of the issues that arose in wake of the *Les v. Reilly* decision. Though the Chamber supports these efforts, we believe that they will result in short-term solutions that, even if implemented, will be subject to constant court challenges. Therefore, we conclude, as did the Ninth Circuit panel, that "if there is to be a change, it is for Congress to direct."

The *Les v. Reilly* decision will have an adverse impact on all links of the food chain, including the most important link — the consumer. The loss of the ability to use a pesticide because it may pose, at most, a negligible risk, will severely hamper our ability to continue to produce an abundant and affordable food supply. At this time, we believe it would be more beneficial to view the current situation not as a crisis, but as an opportunity — an opportunity to construct a bold, progressive, and comprehensive framework for pesticide and food safety policy. In our view, such a policy should include the following elements:

- ▶ a negligible risk standard that is *not* statutorily defined in numeric terms, but defined to represent a level "adequate to protect the public health;"
- ▶ a consistent negligible risk standard applied to raw commodities and processed foods;
- ▶ authority granted to EPA to weigh pesticide use risk *and benefits* when establishing tolerances for raw and processed products;
- ▶ mandated national uniformity of pesticide residue tolerances; and
- ▶ exposure calculations based on the percentage of food (raw commodity or processed) actually treated with a pesticide chemical, and on the actual residue levels of that pesticide chemical.

These essential elements are included in H.R. 1627, the Food Quality Protection Act of 1993. We strongly urge the subcommittee to consider this important legislative proposal as part of its FIFRA mark-up.

CONCLUSION

The Chamber greatly appreciates this opportunity to present its views on FIFRA and related issues and requests that this statement be made a part of the hearing record. We once again commend the subcommittee's leadership on efforts to craft a sensible pesticide and food safety policy. We look forward to working with you on these issues of great importance to the entire chain of food industries.

(Attachment follows:)

The U.S. Chamber of Commerce is the world's largest federation of business companies and associations and is the principal spokesman for the American business community. It represents more than 215,000 businesses, plus 3,000 local and state chambers of commerce, 1,200 trade and professional associations, 65 American Chambers of Commerce Abroad, and 11 bilateral international business councils.

More than 96 percent of the Chamber's members are small business firms with fewer than 100 employees, 71 percent of which have fewer than 10 employees. Yet, virtually all of the nation's largest companies are also active members. We are particularly cognizant of the problems of smaller businesses, as well as issues facing the business community at large.

Besides representing a cross-section of the American business community in terms of number of employees, the Chamber represents a wide management spectrum by type of business and location. Each major classification of American business -- manufacturing, retailing, services, construction, wholesaling, and finance -- numbers more than 11,000 members. Yet no one group constitutes as much as 36 percent of the total membership. Further, the Chamber has substantial membership in all 50 states.

The Chamber's international reach is substantial as well. It believes that global interdependence provides an opportunity, not a threat. In addition to the 65 American Chambers of Commerce Abroad, an increasing number of members are engaged in the export and import of both goods and services and have ongoing investment activities. The Chamber favors strengthened international competitiveness and opposes artificial U.S. and foreign barriers to international business.

Positions on national issues are developed by a cross-section of its members serving on committees, subcommittees, and task forces. Currently, some 1,800 business people participate in this process.

STATEMENT OF GRAY PANTHERS TO
SUBCOMMITTEE ON DEPARTMENT OPERATION AND NUTRITION
JUNE 8, 1993 HEARING CONCERNING PESTICIDE POLICY AND REGULATION

The long-awaited report of the National Academy of Sciences, Pesticides in the Diets of Infants and Children, is a clear signal that the risks associated with our dependency on chemical pest management are intolerable.

Thirty years ago, Rachel Carson's landmark book, Silent Spring, warned that indiscriminate use of pesticides was poisoning the natural world. Recent studies link DDT and other chlorinated hydrocarbons with soaring rate of breast and testicular cancer. A growing body of evidence indicates that these chemicals also disrupt the human reproductive and immune systems. The National Research Council warns that common degenerative diseases, such as Alzheimer's and Parkinson's may be triggered or worsened by chronic, low-level exposure to these pollutants. Brain tumors and leukemia in children are associated with pesticides used in home and garden.

As evidence accumulates, we must conclude in Rachel Carson's words that "we are being asked to take senseless and frightening risks." Urban Pest Management, a 1980 study by the National Academy of Sciences warned of the risks associated with pesticide exposure in the urban/suburban environment. The U.S. General Accounting Office report, PESTICIDES: 30 Years Since Silent Spring--Many Long-Standing Concerns Remain, lists over one-hundred reports from 1968 to 1992, that raise serious concerns about the regulation of pesticides. Yet efforts to strengthen the weak and ineffective Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) have been thwarted by influential economic and political voices--those who would seek to strip us of protection afforded by the Delaney Clause, upheld by the U. S. Supreme Court.

While the major source of pesticide exposure is through food and water, we also experience involuntary contact with these poisons in public buildings, schools, nursing homes, hospitals, restaurants, hotels, parks, and even along highways. Home usage for insect control and lawn care add to the cumulative and multiple exposure. Rachel Carson warned, "The piling up of chemicals from many different sources creates a total exposure that cannot be measured. It is meaningless, therefore, to talk about safety of any specific amounts of residue." Research indicates that continual exposure to small amounts of carcinogens is most likely to cause cancer.

Agrichemical usage has steadily increased despite studies such as the 1989 National Academy of Sciences report, Alternative Agriculture, that find alternative pest management can provide adequate pest control while reducing the use of pesticides and risks of exposure. It is time to challenge those who, for economic gain, have filled our world with poisonous chemicals. As Rachel Carson said, "Who would want to live in a world that is just not quite fatal?" Those responsible will be held accountable to future generations.

REVIEW OF THE REGISTRATION AND REREGISTRATION PROCESS OF THE ENVIRONMENTAL PROTECTION AGENCY UNDER THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

THURSDAY, JUNE 10, 1993

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON DEPARTMENT
OPERATIONS AND NUTRITION,
COMMITTEE ON AGRICULTURE,
Washington, DC.

The subcommittee met, pursuant to notice, at 10:35 a.m., in room 1300, Longworth House Office Building, Hon. Charles W. Stenholm (chairman of the subcommittee) presiding.

Present: Representatives Sarpalius, Dooley, English, Volkmer, Holden, Lambert, Smith, Gunderson, Allard, and Barrett.

Also present: Representative E (Kika) de la Garza, chairman of the committee.

Staff present: Gary R. Mitchell, minority staff director; William E. O'Conner, Jr., minority policy coordinator; John E. Hogan, minority counsel; Glenda L. Temple; clerk, Stan Ray, Rob Wight, Curt Mann, and Pete Thomson.

OPENING STATEMENT OF HON. CHARLES W. STENHOLM, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. STENHOLM. Good morning. This morning we continue the subcommittee's review of the pesticide registration and reregistration processes, which we began earlier this week. Today, our panels will be focusing on a couple of issues that were mentioned frequently in this hearing's first session: The issues surrounding, first, the so-called minor-use pesticides; and, second, alternative pest control devices.

When it is not economically practical for manufacturers to keep chemical products on the market, farmers and other users of those chemicals are the ones who suffer. Products that may be perfectly safe and have met all of the appropriate standards can be pulled out from a farmer's arsenal simply because the marketplace does not provide enough profit to justify going through the tremendous cost of bringing a particular chemical to market and keeping it there. This is a serious problem that must be addressed.

In the first session, we also touched on alternative pest control devices, nontraditional technologies that farmers can add to their options in dealing with pest and weed control. It is not our intent,

at this time, to promote any particular approach. All new methods that promise safe and effective results should be considered, and we hope to begin that process today.

With that, I look forward to hearing your testimony today. Thank you for helping this subcommittee understand better these complex and seemingly controversial matters so that we can begin the work of addressing them.

I recognize Mr. Smith.

OPENING STATEMENT OF HON. ROBERT F. (BOB) SMITH, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF OREGON

Mr. SMITH. Thank you, Mr. Chairman. I think the difficulty of all of this was exemplified in Tuesday's hearing when some of the environmental groups and some of the consumer protection organizations around the country are using as the worst-case scenario the National Academy of Sciences' report on MTD, which in itself, while it was a split decision to even have a report, the report by the National Academy of Sciences quotes this, and I quote: "It is neither perfect nor unalterable"—I'm talking about MTD—"and by itself is insufficient to produce data from which accurate human health risk assessments can be made."

Now, that's the science that we have to depend on, and I suggest it's going to be very difficult to address these issues, Mr. Chairman, when everybody is determined to rely upon science and when science says their material is insufficient to make risk assessment judgments. So somehow we've got to find a source, and, of course, minor use and alternatives are less of a problem, because some of them are not foodstuffs, but it's easy for anybody to attack anything done, because there is no science that's sufficient to support one position or the other.

Thank you, Mr. Chairman.

Mr. STENHOLM. Mr. Dooley.

OPENING STATEMENT OF HON. CALVIN M. DOOLEY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mr. DOOLEY. Thank you, Mr. Chairman. Once again, I applaud you for going forward with these hearings. As we talk about the minor-use issue, I also think we need to give great attention to the public health pesticides that are a part of this minor-use mix. In that regard, this goes right at the heart of the bill that I introduced, H.R. 1867, which is designed to ensure that the American people are adequately protected against the threats to public health posed by mosquitoes and other disease-carrying pests. We're hopeful that we can find ways in which, through the registration process, we can expedite and enhance and also ensure that some of these very vital tools to controlling some of the pests that can contribute to a real public health crisis in this country are available.

Hopefully, through the testimony that we'll hear today we'll get some insight on some of the provisions that need to be a part of any legislation, especially if this legislation is going to be rolled into either the minor-use bill or into a FIFRA reauthorization.

Thank you.

Mr. STENHOLM. Mr. Gunderson.

OPENING STATEMENT OF HON. STEVE GUNDERSON, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF WISCONSIN

Mr. GUNDERSON. Thank you, Mr. Chairman.

I'm not sure how many of you were here at our earlier hearing this week, but I laid out an invitation at that time that I'd like to extend to each of you, including those panelists who will testify after I leave and go to another hearing at the same time. I am a pessimist on FIFRA, I'm a pessimist on this Congress doing anything about FIFRA. One of my colleagues told me I was right, that nothing will get done this session of Congress. I hope they're wrong, and I hope I'm wrong.

I would plead with each of you and invite you to submit to me personally and to this subcommittee any areas where you believe progress can be made in this session of Congress. I will commit myself to working as many hours as necessary, if parties on all sides of this issue really want to get something done. But if we are going to only articulate the polarized positions of the past—and I'm not saying that anybody's position is indefensible—but if we're going to have that kind of environmental gridlock in this session of Congress, then, frankly, I'm going to go on and do something else.

So I invite you to think seriously about how we might be able to make some kind of positive legislative progress on FIFRA in this session and share with us where you believe those areas are.

Thank you, Mr. Chairman.

Mr. STENHOLM. I would like to cheer up my colleague just a little bit. You asked the other day, Mr. Gunderson, what's different this year, and you were gone, and so I wanted to wait until you were here. We have a different administration to work with this year, and, therefore, that is an optimistic sign for me that perhaps some of the gridlock that we've had in the past is going to be gone. I know you share this, that you've already stated you want to work with us on this. I know you do, and I think everybody out there had better be having that spirit of wanting to work together to break this gridlock, because we can't afford to stay in the position we have been in very much longer without doing irreparable damage to the food production system of this country.

Therefore, I'm tempted now, but I want to use the infamous words of Garfield when he said, "He who looks into crystal balls often eats glass," so I'm not going to go quite that far today, Mr. Gunderson, but I do want you to cheer up just a little bit and keep challenging everybody, because you're right on track with the challenge. There is one change, and, therefore, let's give that one a chance.

Mr. GUNDERSON. I thought you were going to say the change was a new chairman of this subcommittee.

Mr. STENHOLM. I knew better than that.

Mr. GUNDERSON. I promise not to make you eat glass. I hope you're right. [Laughter.]

Mr. STENHOLM. That is another change. We are very dedicated to bringing this issue to a successful culmination in this Congress,

and the challenge is there. I'll recognize Mr. Sarpalius, before I make another comment along that line.

Mr. SARPALIUS. Nothing, Mr. Chairman.

Mr. STENHOLM. No comment there.

Mr. Volkmer.

Mr. VOLKMER. No comment. I like to come here to listen to the witnesses and not the other members. [Laughter.]

Mr. STENHOLM. We'll call the first panel. [Laughter.]

The first panel will come to the table: Mr. Brown, Mr. Guest, Mr. Maslyn, Mr. Botts, and Mr. Hazeltine. I'd remind each of the witnesses that your entire testimony will be made a part of the record, and we would appreciate your summation. I would instruct the clerk to allow everyone up to 10 minutes.

We welcome each of you here. We appreciate you being here. We first recognize the Honorable Arthur R. Brown, Jr., secretary of agriculture, New Jersey Department of Agriculture.

Welcome, Mr. Secretary.

STATEMENT OF ARTHUR R. BROWN, JR., SECRETARY OF AGRICULTURE, NEW JERSEY DEPARTMENT OF AGRICULTURE

Mr. BROWN. Good morning, Mr. Chairman, and members of the subcommittee. As New Jersey's secretary of agriculture, I want to thank you for the opportunity to testify on behalf of both NASDA and the State of New Jersey. NASDA, the National Association of State Departments of Agriculture, is a nonprofit, nonpartisan organization comprised of the 50 State departments of agriculture and those from Puerto Rico, Guam, American Samoa, and the Virgin Islands.

Many State departments of agriculture regulate the use of pesticides. In any case, all agricultural departments will have to deal with the far-reaching and potentially devastating effects of products lost because of the economics of the reregistration process. The issue of the reregistration and registration of pesticides is much more complex than it may appear.

Since the Federal Insecticide, Fungicide, and Rodenticide Act, known as FIFRA, was enacted in 1947, over 50,000 pesticide products have been registered. By amendment in 1972, FIFRA requires EPA to reevaluate registered pesticides, taking into account long-term health and environmental effects. The resulting reregistration requirements only made the process more complex, in some cases prohibitively expensive and probably impossible to accomplish in our lifetimes.

A 1997 deadline was set for the completion of most pesticide registration decisions by EPA. As you heard Tuesday, EPA has reached final decisions on only 20 or 30 of the more than 20,000 products subject to reregistration. The reregistration requirements have already resulted in many voluntary cancellations by registrants. In particular, minor-use pesticides are endangered for economic, not safety, reasons. The reregistration process simply costs too much and takes too long.

Mr. Chairman, I think it is appropriate to put the term "minor-use crops" in its proper "major" perspective. In 1990 U.S. agricultural crop sales were valued at approximately \$70 billion. Almost one-half of that figure came from sales of crops like vegetables,

fruits, and nuts, all of which fall under what I consider a misnomer—minor crops. In many States these so-called minor crops are a significant percentage of the value of all crops. In my own State of New Jersey, for example, according to 1987 data, these minor crops accounted for \$360 million in agricultural sales. That's 85 percent of the value of all crops in New Jersey.

We must change our policies to assure continued production of these so-called minor crops through the availability of safe, effective pesticides or other alternatives. Unfortunately, the prospects for new replacement products and nonchemical alternatives are few, if any, because the costs of research, development, and registration exceed the potential dollar value of the market.

Research has shown that 99.99 percent of all dietary pesticides are naturally produced by plants. Most Americans consume about 1,500 milligrams of these natural pesticides each day. In contrast, FDA's residue studies show that most people ingest a daily average of less than one-tenth of 1 milligram of synthetic chemicals, including synthetic pesticides. Based on this evidence, I believe that the amount of information required for pesticide registration under section 6(a)(2) of FIFRA is too extensive, unjustifiably costly, and unnecessary and will cause the registration process to be unworkable.

Mr. Chairman, I know that other bills have been proposed in the current Congress on that issue. With regard to these bills, I would like to state for the record that I support H.R. 1627, the Food Quality Protection Act of 1993. I also strongly urge the subcommittee to pass H.R. 967, the Minor Crop Pesticides Act of 1993, which amends FIFRA.

Several provisions in the amendments will help the agricultural industry. For example, registrants would be providing an additional 10 years of exclusive use data to support a minor use. EPA would have to review and decide on applications for minor-use pesticides within 6 months of submission. Necessary resources would be provided to USDA to assist with minor crop issues, and resources would be provided to both EPA and USDA to assist in registering and reregistering minor-use chemicals.

This is not just a farmer issue. Significant financial impacts would also be felt by processors and consumers. Thus, consumers could see fewer fresh fruits and vegetables, lower-quality produce, and higher prices in the marketplace. I believe that H.R. 967 maintains essential safeguards for public health and the safety of the food supply while providing significant benefits to both agriculture and consumers.

In New Jersey pesticide applications are regulated by the New Jersey Department of Environmental Protection and Energy. That agency agrees with my request that your subcommittee take the following actions: One, establish a clearinghouse which would serve as a one-stop center for registrants to get answers on questions concerning registration and reregistration; two, enhance the existing IR-4 program, which has generated useful data for registering pesticides used for minor crops, as will be shown in the testimony from Dr. Richard Guest, national director of the IR-4 project, which is coming up next; three, support integrated pest management programs similar to the one based at Rutgers Cooperative Extension Service in New Jersey and strongly supported by the New

Jersey farmers. Based on the data from this program, recommendations are made so that pests can be properly managed and pesticide applications reduced. Cancellation of the pesticides on the EPA list will hurt this program and impact on its goal of careful pesticide use. And, four, provide for an expedited process for registration of pesticide products that are considered low risk, such as biologicals, which may provide alternative tools needed for minor crop production.

Once again, I remind you not to be misled by the term "minor use" as it applies to either pesticides or the crops they protect. These crops account for nearly one-half of the total agricultural value of our Nation's crop sales. Moreover, many of these are the very crops that medical and scientific researchers are encouraging us to eat to improve our health and longevity. It would be a cruel twist of fate if bureaucratic requirements with little basis in science or fact were allowed to jeopardize our access to these vital products.

All subcommittee members have received copies of my written testimony, which goes into greater detail on some of the points that I've made. I certainly would be happy to answer any questions from the subcommittee at the conclusion of this panel discussion.

I want to thank you very much for your time, Mr. Chairman, and the subcommittee members.

[The prepared statement of Mr. Brown appears at the conclusion of the hearing.]

Mr. STENHOLM. Thank you very much, Mr. Secretary.

Next we'll hear from Dr. Richard T. Guest, national director, interregional research project No. 4, Rutgers University.

Dr. Guest.

STATEMENT OF RICHARD T. GUEST, NATIONAL DIRECTOR, INTERREGIONAL RESEARCH PROJECT NO. 4, RUTGERS UNIVERSITY

Mr. GUEST. Mr. Chairman and members of the subcommittee, thank you for the opportunity to speak on behalf of the IR-4 project on the operation and effectiveness of this program. My name is Richard Guest, and I serve as the national director of IR-4. In the interest of time, I will briefly present highlights from my prepared statement.

I have just returned from an international symposium on minor uses in Germany. I was invited to this symposium to present a paper on the organization, operation, and accomplishments of the IR-4 project. Common market nations are now recognizing the seriousness of the minor-use problem and are seeking solutions. They have heard of the U.S. minor-use program and are anxious to learn more of it. In his concluding remarks, Dr. Frederick Klingauf, the chair of the symposium stated that IR-4 is an effective program and could well serve as a model for the European Community nations.

Minor crops are, of course, very important to U.S. agriculture. The value of minor crops is estimated to be more than \$24 billion annually, or about 40 percent of all agricultural crop sales. One-half of all States have minor crop sales equaling or exceeding 50 percent of their total annual crop sales.

The IR-4 project was initiated in 1963 by directors of State agricultural experiment stations to address the minor-use needs. IR-4 has evolved into a cooperative effort between EPA, USDA, State agricultural experiment stations, the Cooperative Extension Service, agricultural chemical companies, commodity organizations, and individual growers. The program includes a management team consisting of an administrative committee and a technical committee, each made up of representatives from State land-grant universities and from USDA, and a national director who is employed to coordinate the overall minor-use program.

Minor-use clearance requests are submitted to IR-4 by State and Federal scientists, by Extension specialists, by commodity organizations, by individual growers. Each clearance request is carefully reviewed to assure equal consideration for all segments of agriculture. Priorities are set annually at regional and national workshops attended by State and Federal scientists, commodity producers, and agricultural chemical company representatives. Reviews include consideration for need, for effectiveness, for the importance of the pest problem, for alternatives, for possible data gaps, and for the value in IPM programs. Cooperators to carry out the research program are sought among State and Federal scientists, with assistance from private contractors. Analysis of residue samples are carried out by IR-4 regional leader laboratories.

All research is conducted according to Good Laboratory Practice Standards. Data are incorporated into a tolerance petition by IR-4 headquarters personnel and is submitted first to the prospective commercial registrant for concurrence and then to EPA for review and approval. Once the tolerance has been established, the registrant adds the new use to the product label.

IR-4 also carries an ornamentals registration program and a biorationals registration program. These programs operate in a similar manner to the food use program.

FIFRA '88 has had a significant impact on the IR-4 minor-use program. Extensive surveys in 1989 strongly suggested that the combined effect of a minor-use reregistration and an increasing backlog of new minor-use registrations would at least quadruple the workload of IR-4. In response, IR-4 developed a strategic plan to increase the number of annual project completions to about 500 a year. The strategic plan called for a substantial increase in both field and laboratory capabilities, the additional funding for ornamentals registrations, and an increased commitment to biological registrations.

The initial cost of the plan was put at \$12 million per year based on a 1990 start-up date. This figure has been subsequently revised to \$14 million a year. Funding available from USDA for fiscal year 1993 is \$6.1 million. USDA's CSRS has requested an increase of \$6.5 million in the fiscal year 1994 budget. Federal funds are leveraged about 3:1 by host research institutions through direct and indirect resources. Additional support is also provided by EPA, by commodity organizations, and by agrichemical registrants.

Since the beginning of the program through calendar year 1992, IR-4 has cleared 4,157 food uses, or 138 clearances each year. The ornamentals program has been responsible for more than 3,600 pesticide registrations since it was established 16 years ago. The

biologicals program has contributed to eight of the biorationals currently registered by EPA.

In conclusion, IR-4 has been responsible for one-half of all pesticide registrations on minor food crops and 80 percent of all pesticides registered on ornamentals. The success of IR-4 is attributable mainly to the cooperative nature of the program, which brings together Federal and State agencies, commodity producers, agricultural chemical registrants, State and Federal scientists, and a team of IR-4 coordinators, all working together for a common purpose.

Mr. Chairman, thank you for this opportunity to present this testimony. I would be happy to answer questions.

[The prepared statement of Mr. Guest appears at the conclusion of the hearing.]

Mr. STENHOLM. Thank you.

Our next witness is Mr. Mark Maslyn, vice chairman, Minor Crop Farmer Alliance, and director of governmental affairs, American Farm Bureau.

Welcome, Mark.

STATEMENT OF MARK MASLYN, VICE CHAIRMAN, MINOR CROP FARMER ALLIANCE, AND DIRECTOR, GOVERNMENTAL AFFAIRS, AMERICAN FARM BUREAU FEDERATION

Mr. MASLYN. Thank you. Mr. Chairman and members of the subcommittee. We appreciate the opportunity to testify on behalf of the Minor Crop Farmer Alliance. A written statement has been submitted for the record, and we will summarize our remarks.

I'd like to take a moment to describe the origins of the membership of the Minor Crop Farmer Alliance and the overall problem which our members now face. Dan Botts, who chairs the technical committee of the Minor Crop Farmer Alliance, will describe the specific recommendations in detail.

The minor crop problem, as has been stated several times this morning, involves the loss of valuable and safe crop protection tools for production agriculture due to economic reasons. Simply stated, the data requirements imposed on pesticide manufacturers to support their pesticide registrations represent a substantial investment. Regrettably, for a number of the pesticide uses, registrants have determined that the value of the sales are insufficient to support the product through data development.

Under such circumstances, the inclination of the registrant is to voluntarily cancel the products and also not to seek new uses. That's an important point that is often overlooked. We're talking about products that are on the market as well as products that are in the pipeline, that are in research and development. Farmers often depend on more than one crop protection tool to address a pest problem in order to avoid pest resistance build-up and to sustain integrated pest management programs. Consequently, to the extent that these tools are lost, serious impacts are being experienced by farmers. In response, we want to ensure that farmers, when they are threatened with the loss of a critical crop protection tool, have the chemical or nonchemical alternatives available.

In the summer of 1991, farmers and farmer representatives met in Dallas, Texas, and also at the American Farm Bureau offices in

Chicago, Illinois, to discuss the growing problem and the implications to agriculture. With the interest increasing, a broader coalition met at the offices of the United Fresh Fruit and Vegetable Association in the fall of 1991 and agreed to form the alliance and to begin to develop solutions to address the minor-use problem. A list of our current members is attached to our written statement.

The alliance is increasing and is comprised solely of production agricultural interests. We have the sole objective of addressing the minor-use problem while continuing to preserve the authority of the EPA in the area of health and safety. Essentially all of our proposals are compatible with the goals and timetables of the 1988 FIFRA amendments. This is not a new problem. It was anticipated prior to the FIFRA amendments of 1988. It is here now, and it will get worse if we fail to take action this year. This problem has become very acute and will reach a critical phase over the next year or so as the data reviews are completed by EPA. The number of uses to be dropped will greatly increase.

We have conducted a State-by-State survey, which we have distributed to all members of the committee to illustrate the extent of this problem, and the results of the survey, we think, show that this is not a local problem, this is not a problem confined to any one State or any one region. It affects virtually every region and every State in this country.

In general, we propose to address the minor-use problem in the following ways: First, by providing incentives to registrants to continue to register and reregister safe chemicals for minor uses; second, by providing incentives and resources to the EPA to assist in registering and reregistering minor-use pesticides; and, third, by providing necessary resources to USDA to assist minor crops. This will be accomplished by accelerating the development of crop protection tools, both chemical and nonchemical, and assuring more focused research on minor crop issues. And, finally, by providing more effective coordination of existing programs and efforts within the Department.

Mr. Dan Botts of the Florida Fruit and Vegetable Association will now briefly summarize the specific recommendations in H.R. 967.

STATEMENT OF DANIEL A. BOTTS, CHAIRMAN, TECHNICAL COMMITTEE, MINOR CROP FARMER ALLIANCE, AND DIRECTOR, ENVIRONMENTAL AND PEST MANAGEMENT DIVISION, FLORIDA FRUIT & VEGETABLE ASSOCIATION

Mr. BOTTS. Mr. Chairman, as indicated by Mr. Maslyn, we endorse the suggested legislative approaches now embodied in H.R. 967, introduced by Chairman de la Garza, Representatives Stenholm, Roberts, and Smith, and over 85 other House Members. However, there is no guarantee that the minor-use problem will disappear if all of these proposals are implemented. Short of mandating minor-use registrations, which we do not believe is possible, no such guarantee can be given. We believe that the suggestions in H.R. 967 as a whole will significantly ease the problem.

Before reviewing the specific proposals, perhaps it would be helpful to provide an example of the type of problem we as an industry are dealing with. Lettuce production on organic soils in Florida,

which is approximately 5 percent of the total annual U.S. production, is concentrated in two production regions of Florida: One being south of Lake Okeechobee in south Florida, and the other being north of Lake Apopka in central Florida. The total acreage of these production areas averages between 12,000 to 15,000 acres annually.

One of the major production problems to be overcome is competition from weeds during the early stages of crop growth. This industry has been searching for an answer to this production problem since the voluntary cancellation of the product CDEC in 1979, which predates the current reregistration situation. In addition to herbicidal tools, growers have examined modifications to existing cultural practices, including changes in crop rotation patterns, flooding of fallow fields during the summer fallow period, mechanical cultivation, and hand weeding, as alternatives to reliance on herbicidal control. None of these nonchemical alternatives provides the level of consistent management of weeds to be the total answer to this production problem.

In cooperation with the Institute of Food and Agricultural Sciences at the University of Florida and the IR-4 program, a new class of herbicides was identified that had been registered for use on soybeans in the late 1980's, which appeared to resolve this problem. After consultation with the registrant, the IR-4 program, and EPA, the data needs to expand the label to include lettuce were identified, and the estimated cost to provide this data was over \$400,000. Development of the data would potentially open the door to enter a market that represents a potential return to the registrant on an annual basis of approximately \$60,000. This economic scenario, coupled with the potential liability associated with its use on lettuce, resulted in the growers of Florida accepting the responsibility to fund the data generation necessary to allow expansion of the label for this product.

In 1990 eight growers, representing 98 percent of that lettuce production in Florida, pledged the funds necessary to generate the data. The following studies were contracted and performed at the growers' expense: A plant metabolism study, four individual magnitude of residue studies in Florida, storage stability studies for those products after they had been harvested, and an analytical method validation to ensure that there would be an enforcement method that was appropriate. The data package was completed in 1992. The results were provided to EPA and to IR-4 for development of a petition to establish the tolerance package for lettuce for this product.

During the 3-year period of this project, three of those eight growers made the decision that lettuce was no longer a viable component in their production picture, primarily because of the fact that the hand weeding cost during that period averaged between \$300 and \$700 per acre. Not only was this cost added to it, but also each time the hand weeding crew went through the field, there was a corresponding 8 to 12 percent reduction in potential yield. It's anticipated that once this label is obtained, those lettuce growers will again move back into production of this commodity.

In discussing the specific recommendations embodied in H.R. 967, let me reemphasize the overall approach which the alliance

utilized in addressing the minor-use issue. First, we wanted to be certain that any measures proposed were consistent with assuring that there were no unreasonable adverse impacts on human health and the environment from maintaining a particular minor use, and, second, we wanted to focus on developing a series of incentives or removing current disincentives for the manufacturers of the products we were seeking to get registered to support these minor uses.

In developing these incentives, we believe it is necessary to develop a definition of minor use. We propose that minor use be defined as the use of a pesticide on an animal, on a commercial agricultural crop or site, or for the protection of public health where, one, the EPA Administrator, in consultation with the Secretary of Agriculture, determines that based on information provided by an applicant that the use does not provide sufficient economic incentive to support the initial registration or continuing registration of a pesticide for such use; and, two, the EPA Administrator has not determined that based on existing data such use represents a risk of an unreasonable adverse effect on the environment.

If a particular use falls within the definition of a minor use, then such use would be eligible for consideration under the operative provisions of the proposals embodied in the legislation. These provisions are as follows: First, registrants would be provided an additional 10 years of exclusive use of the data which was generated solely to support a minor use; second, the Environmental Protection Agency would be instructed to review and act on, within 6 months of submission, applications for new chemicals that meet one of the following criteria: (a) Would be registered for minor uses only; or (b) represents a submission that has a major use with a significant number of minor uses. Currently, we're looking at somewhere between three or more minor uses or replace chemicals canceled within the preceding 5 years or replace one being issued under emergency exemption under section 18.

The third provision would be if a minor-use waiver request made by a registrant was denied by EPA because additional data was required, the EPA is instructed to grant the registrant the original full-time period for providing the further data. EPA may deny the time extension request if it determines the data waiver request was not made in good faith or deny or revoke the extension if the Administrator determines an adverse environmental impact or significant delays could result in the schedule for issuing a reregistration eligibility determination. The fourth provision, if a pesticide is being reregistered for minor uses as well as other uses, the EPA would be required to extend the deadline by up to 2 years for the production of residue chemistry data required solely to support the minor-use of a pesticide. This is provided that the registrant is providing all the data necessary to support the other major uses of the pesticide.

The fifth provision would allow for a voluntarily canceled minor use, a registrant would be authorized to make the effective date of voluntary cancellation coincide with the submission of the data for those uses not being canceled. This would provide a transitional period for minor uses to allow the determination of whether effective alternatives exist or how to best address the pest or disease prob-

lem. The sixth provision would be that even if a voluntary minor-use cancellation has occurred, supporting data from previous registration can be utilized for a period of up to 2 years to register the chemical when an application for a similar minor use is made.

The seventh provision, EPA is required to utilize its authority to grant conditional registrations of a minor-use of a pesticide when the use would not significantly increase the risk of any unreasonable adverse effect on the environment. The last provision included a new minor-use program to be established within USDA, and existing USDA and EPA resources and programs affecting minor uses would be enhanced and more effectively coordinated.

The alliance recognizes and is extremely supportive of the Interregional Research Project No. 4, IR-4, of USDA. This program has not been given the priority it deserves for funding either at the Federal or the State level. Many members of the Minor Crop Farmer Alliance have worked cooperatively with IR-4 in the development of the data necessary to support tolerances which can lead to food crop use registrations, and several MCFA members are directly involved on IR-4's commodity liaison committee. The IR-4 program has also been invaluable in the expansion of uses of products registered for turf and ornamental uses.

The IR-4 program alone cannot fully meet the needs of the agricultural community, but it is a very important component in the regulatory process. Over the past several years, IR-4 has received inadequate funds to deal with the ever-increasing regulatory burden associated with residue and crop efficacy studies. As with EPA and its increased workload due to reregistration, IR-4 has had to deal with increased regulatory requirements under a decreasing funds scenario. In recognition of this fact, the legislature authorized funding of up to \$25 million per year in the 1990 farm bill. Even if this funding level was available, the backlog of petitions already in place and the necessary enhancement of the laboratory capability would not allow an immediate impact on the overall long-term problems associated with minor uses of pesticides.

We feel that the MCFA legislative package will work in concert with the existing IR-4 structure to facilitate and streamline the data generation process to make IR-4's task as efficient as possible under the complex regulatory process dictated for pesticidal products. We believe the above-mentioned legislative, regulatory, and resource changes would be a positive step forward in addressing the minor-use problem.

Unless Federal policy is changed quickly, production agriculture in the United States will not have the necessary tools to efficiently bring a safe, abundant, varied, and affordable supply of food and other farm products to American consumers. The Alliance looks forward to working with you and the subcommittee to implement these changes as quickly as possible.

I thank you.

[The joint prepared statement of Mr. Maslyn and Mr. Botts appears at the conclusion of the hearing.]

Mr. STENHOLM. Thank you.

Next we'll hear from Dr. Hazeltine, representing the American Mosquito Control Association.

STATEMENT OF WILLIAM HAZELTINE ON BEHALF OF THE AMERICAN MOSQUITO CONTROL ASSOCIATION

Mr. HAZELTINE. Mr. Chairman and members, our members have understood and practiced integrated pest management before that term became popular. As a consequence, we recognize the need for effective pesticides in our programs, which rely on prevention as well as control. Our association members pioneered the use of biological control by the manipulation of mosquito fish, by the manipulation of water levels, and the safe and effective use of natural and synthetic pesticides. Our members continue to lead in this area of comprehensive control of public health pests.

However, our ability to provide effective and acceptable programs is continuing to erode.

It should be obvious that for good IPM programs to continue, we need to have a wide array of choices available to us so we can select the best material or method when control becomes necessary. Once again, we ask you to recognize that we use pesticides to protect people and that balancing of the risks and benefits required under FIFRA should recognize this benefit of human health protection. Our request is that this subcommittee acknowledge that public health pesticides should come under a separate set of risk/benefit balances and amend FIFRA to include a separate class of pesticide registration to accomplish this need.

We thank Congressman Dooley for introducing H.R. 1867, which would make the following changes in FIFRA: First, it would define minor use and include public health pesticide uses in the context of that definition; second, it would create a separate class of pesticide registrations for public health pesticides with a risk/benefit balance which is separate from the balance which is utilized for agricultural pesticides; third, require that the EPA Administrator take into consideration the differences between agricultural, non-agricultural, and public health pesticides; fourth, require consultation by the EPA Administrator with the Secretary of Health and Human Services comparable to the consultation which now takes place with the Secretary of Agriculture, and to require annual reports on vectors, diseases, and pesticides used to control diseases; and fifth, to expedite registration of products necessary for public health protection.

In order to provide back-up information for any subcommittee members who were not here 2 years ago, I've included copies of the testimony presented at that time, which have been updated. I would call your attention to the table, which points out the additional loss of materials that we've experienced in the 2 years since that testimony was given.

Also included in the package of materials we submitted to you are a few pages from a book written in 1992 for the Institute of Medicine, which is entitled "Emerging Infections: Microbial Threats to Health in the United States." The conclusion of the section on vector control says, "The committee recommends that additional priority and funding be afforded efforts to develop pesticides—and effective modes of application—and other measures for public health use in suppressing vector-borne infectious diseases." We appreciate this recognition of the need for the legislative proposals we have been advocating, and we ask this subcommittee to support the

Institute of Medicine's recommendations by acting favorably on H.R. 1867.

In Tuesday's testimony there was some reference to physiological resistance to pesticides. The experts tell us that the best way to avoid resistance is to have a wide arsenal of materials to choose from, and the best way to encourage resistance is to limit the number of pesticides available for use.

There are some additional issues which we hope you can address in your general legislation. Let me give some examples. First, residue tolerances need to be uniform in all 50 States. The issue of residue tolerances should also recognize the need for keeping standards reasonable. The proposal of EPA to establish de minimis tolerances even for carcinogens in cases where amounts of pesticide residues are so low that they are insignificant should be legislatively supported. This would help relieve a problem for us where we do not treat a crop; we only treat the air above it or the water below it, but we do nothing to further the productivity of that agricultural commodity.

Incidentally, it seems to us that water which is available as a potable water supply fits the definition of a processed food and, therefore, might come under the Delaney amendment, and, if strictly enforced, perhaps we would have to suffer enteric diseases from the problems created by nontreatment of that water from chlorination. We do not advocate the ending of the chlorination process..

Continuing on tolerances, the doses of pesticides which we use are so much lower than those used for crop production that there needs to be a different standard established for our practices, which will allow our control of disease vectors without having to ask the producer to expend millions of dollars doing studies when the amounts of residue which we may create may be insignificant. During the questioning period, I'd be happy to provide additional information on this topic, if you care to ask.

Second, there should be a measure of Federal preemption on pesticide use. Mosquitoes and other vectors don't recognize political boundaries, and it makes no sense to be allowed to apply a pesticide up to the edge of a town or city and not be able to apply the same material to control the same vectors across some imaginary line. Similarly, vectors being produced inside a no-spray zone or even across a State border can fly out to infect people outside that zone or State, and control agencies would not be able to treat the breeding place, which in many instances is declared a public nuisance, under a no-spray limitation. Individuals' rights are worthy of protection, but the rights of their neighbors must also be protected. When the issue is protection from disease vectors, the rights of the individuals to have disease protection should be given some added emphasis.

Another point. We are constantly being told about the potential dangers and adverse impacts of pesticides on wildlife, but there is little, if any, recognition of the problems of wildlife which may be relieved by these same pesticides. Third, besides protecting people from disease, a new area involves our understanding that pesticides also have a beneficial effect on some endangered or rare animals under the Endangered Species Act. Evidence now shows that some of the endangered birds and mammals are subject to some of

the same virus diseases which cause diseases in humans and which are transmitted by mosquitoes and related vectors.

A famous example is the death of the endangered whooping cranes which were in a captive breeding program in Patuxent, Maryland. In 1984, 30 percent of those captive breeding birds died from eastern equine encephalitis, a disease that is only vectored by mosquitoes. Incidentally, rather than control the mosquitoes, they vaccinated the birds, but when those birds are introduced back into the wild, obviously they will not carry any immunity to their offspring.

Eastern equine encephalitis is the same virus that was found in 14 percent of the collections of imported Asian tiger mosquitoes collected in Polk County, Florida, last year during a human epidemic of eastern equine encephalitis.

Obviously, effective insecticides are part of any comprehensive vector control program, even in areas where rare or endangered wildlife may exist.

Other endangered or threatened species for which there's evidence to suggest problems include sandhill cranes, kangaroo rats, harvest mice, cotton rats, tricolored blackbirds, bighorn sheep, and bald eagles. We would also suggest to you that if anybody bothered to look, they probably would find a much larger number of endangered species that are subject to these diseases.

The Fresno kangaroo rat is an excellent example. That particular rat likes the alkaline ground that is found in the southern San Joaquin Valley of California. However, that ground is not good for agricultural production, so the highest and best use of that ground has been to flood it for duck clubs. However, when that ground is flooded around the rat habitat, the production of mosquitoes and the invitation to birds to fly in and carry the virus, creates a serious risk for those endangered species.

So failure to keep mosquito control pesticides available for use appears to have a potential, if not an actual, adverse effect on endangered species as well as people. Failure of EPA to help us control mosquitoes could even be seen as an action detrimental to the preservation and enhancement of endangered species and, therefore, perhaps a violation of the Endangered Species Act. This is something that we may be able to use to advantage.

Game birds and mammals are also subject to a wide variety of insect vectors and diseases which might be reduced by appropriate pesticide use. A good example is the periodic epidemics of eastern equine encephalitis in pheasants in the Midwest where whole flocks can be wiped out. Only mosquito control can prevent these losses.

We're constantly amazed at the way the benefits of pesticides are neglected in the rush to find any adverse effect which might be used as a reason to ban pesticides.

We thank this committee for the opportunity to testify about this very important subject, and we ask you to give serious consideration to the needs which we have and to support H.R. 1867.

We are suggesting that H.R. 1867 might be added to the de la Garza bill, in the future, to create a more comprehensive minor-use bill when that bill is reported by the subcommittee.

We're anxious to respond to Mr. Gunderson's concerns and work with EPA or anyone else to reach a consensus as long as we are asked to play on a level field. We'd be happy to help EPA understand the benefits for their risk/benefit determinations, and we would suggest that there needs to be someone to facilitate this meeting of people and discussion of the issues. I don't think it will be done on our initiative and theirs. I think perhaps Mr. Gunderson, who has pledged himself, might be an appropriate person to bring everybody into the same room and try to find those solutions, but we're pledged to working with whoever would be able to help understand and bring these things to a point of resolution.

Thank you very much.

[The prepared statement of Mr. Hazeltine appears at the conclusion of the hearing.]

Mr. STENHOLM. Thank you, and thank the entire panel for some excellent testimony, some very constructive suggestions on the way in which this subcommittee should proceed. We appreciate it.

Mr. Sarpalius.

Mr. SARPALIUS. Thank you, Mr. Chairman. I have one question to Secretary Brown.

What impact will the Food Quality Protection Act have on the registration and reregistration process, and how will it decrease the number of pesticides that are classified as high risk?

Mr. BROWN. In the State where I come from, we're dealing with primarily all fresh market vegetables, and certainly we abide by the tolerance levels that have been established and the residues that have been established, but we have a lot of what we call real minor crop, and it could put us right out of the ballpark. When we start growing parsley and arugula, and cardoon, things that people have never heard of, we are looking for special control on insects and disease on these products. So we certainly need a lot of these pesticides for control of insect and disease on those products.

Certainly the risk that we see right now is that there is a very negligible risk with the products that we have in mind. I don't think that we're opposed to cutting some of these products out which they call high risk, providing we have a replacement to come along to satisfy the needs of producing a high-quality crop with another type of pesticide. But we certainly feel that as we go along through the ages here, biological control has an awful lot of promise for the future.

In our own State we are working very diligently with biological control, but it's something that doesn't happen overnight, and we need certainly replacement, but we can't expect to just cut out some of these programs immediately and not have anything as an alternative to go to. So it's important that this program be looked at very seriously and given some extra time to reregister these products.

Mr. SARPALIUS. When you hit on biological control, it's kind of interesting how many people probably don't understand the value of that. There's a laboratory at Texas Tech University that the chairman and I both have worked hard on trying to obtain funds for that deals with plant stress, and there was a group here in Washington that thought that was a great area where we were wasting money, that we shouldn't be funding anymore, that couldn't under-

stand why the Federal Government was spending all this money on studying the emotional stress of plants, when in reality the laboratory's there to see how plants can do with drought resistance and things like that.

As we look into the future of genetic engineering and some of the other areas that we hope to someday truly have some disease-resistant plants, drought-resistant plants, do you think that we are being as aggressive in researching in these areas as other countries have been, and are we heading down the right path? Are we not being as aggressive, or are we doing OK?

Mr. BROWN. Let me continue on that, Mr. Sarpalius. I think that one of the problems that we have, and you hit on it, is the money for research. We keep on striving to cut down on the amount of pesticides released into the environment, and we have a strong biological program and biotech program in this country that we could really do a lot more than what we're doing, but one of the first places to cut is research, and we're talking about a goal, but we don't want to fund that goal.

I think that something needs to be done as far as research at the—I certainly work for State government, but I've been involved in Extension, and I think that Extension has proven itself over the years and has been an integral part of agriculture and something that's been a strong building block of a strong agriculture, and I think that the State land-grant universities, again, should be funded.

I know when Dr. Hess was here from California and also from New Jersey, they were working on a program to get extra dollars into research for getting involved with putting in the biotechnology for drought resistance, insect resistance, disease resistance. It's there, and what we have to do is spend some time and money, and we can put it in place.

Mr. SARPALIUS. Do you think we're working aggressively enough in that area?

Mr. BROWN. No, I don't think you are.

Mr. SARPALIUS. Dr. Guest, when you looked at the European countries, did you find much work in that area? And also, just briefly, as we look at the NAFTA, one of the big concerns in there is our country meeting all these environmental concerns relating to chemicals and the problems our farmers have to deal with. Is there any assurance that Mexico would be enforcing those type of requirements of its farmers as well?

Mr. GUEST. Let me address the first question. I had the good fortune of touring the biological research center in Braunschweig that does all kinds of agricultural research, and they have a program that goes all the way from the very applied, which would include certification of sprayers, to the very fundamental, which would include genetic engineering, and they are dedicating a considerable amount of resources and effort to the biological area. They think that is a very important aspect of their pest control program in Germany and, I expect, other European Community nations as well.

I really don't think I can answer your question concerning Mexico. Our experience outside the shores of the United States has been very limited. But I would have to say that in 1982 the IR—

4 project adopted a biorational research objective, and we have been very much interested in this area and think it is a very important area, and we think we have a position to play in the minor crop area in terms of registering microbials and biochemicals that require exemptions according to EPA regulations.

Our experience has been that this is a very expensive and time-consuming kind of research, and in my testimony I cite one example of a petition we just recently submitted on the codling moth granulosis virus for use primarily in California. That research program took 10 years. It took us into the toxicology area. It was jointly funded by IR-4, the State of the California, some environmental groups, and individual growers, and it cost over \$10 million, but it was a very expensive, time-consuming program.

We would like to see things move a little bit faster in the biological area. In order to move into that area more rapidly for IR-4, our technical committee has voted to earmark 15 percent of all research budgets over and above our \$3.5 million base funding level for biological control. I think that demonstrates our commitment to the biological aspect of the minor crop program.

Mr. STENHOLM. Mr. Smith.

Mr. SMITH. Thank you, Mr. Chairman.

Dr. Hazeltine, I was interested in your testimony regarding the impact upon endangered species of the outbreak of mosquitoes in particular. Tell me, in the last 5 years, in your experience, what outbreaks of diseases have been caused by vectors to humans that may have been controlled by proper use of control mechanisms?

Mr. HAZELTINE. Within the approximate last 5 years—I'm going from memory—Florida in 1992, I believe, had the outbreak of eastern encephalitis. Prior to that time, Florida had an outbreak of St. Louis encephalitis. This was the problem that created havoc with Disney World and the tourist economy and also created havoc with people. There have been other outbreaks. Luckily, they've been small. Our work is to prevent these problems, and we do our best to work in that prevention area. However, the threat is there, and it is continuing.

California in the past has had some of these problems, Texas, various places. I will supply some material for the record.

[The material follows:]



AMERICAN MOSQUITO CONTROL ASSOCIATION, INC.

707-A East Prien Lake Road, P. O. Box 5416, Lake Charles, LA 70606-5416

Telephone (318) 474-2723

FAX (318) 478-9434



1993-1994 BOARD OF DIRECTORS

OFFICERS

Dr. John Mulrennan, Jr.

President

Dr. Chester G. Moore

President elect

Dr. John Edman

Vice President

Cyrus R. Lesser

President 1992

Matthew M. Yates

President 1991

John S. Billodeaux

Treasurer

REGIONAL DIRECTORS

Dr. Barry Tyler

Canada

Dr. Kenneth Ludlam

North Atlantic

Dr. Bruce Harrison

Mid-Atlantic

Edgar Hughes

South Atlantic

Sally Wagner

North Central

Dr. Daniel D. Sprenger

South Central

Dr. Sammie Lee Dickson

West Central

Peter DeChant

North Pacific

Dr. Charles Beesley

South Pacific

Dr. Marco F. Suarez

Latin America-Caribbean

William J. Zawicki

Industry Director

CENTRAL OFFICE STAFF

Pamela Toups

Mgr. of General Services

Lucas Terracina

Interim Exec. Director

Dr. Harold C. Chapman

Exec. Director Emeritus

Thomas D. Mulhern

Exec. Director Emeritus

EDITORS

Dr. Ronald A. Ward

JOURNAL OF AMCA

Dr. Lewis T. Nielsen

Dr. Ralph Harbach

MOSQUITO SYSTEMATICS

Dr. Jimmie D. Long

NEWSLETTER

June 29, 1993

Department of Operations and Nutrition Subcommittee
of the House Committee on Agriculture
Longworth Office Building, Room 1300
Washington, DC 20515

Dear Committee Members:

The enclosed information on the occurrence of arboviruses, lyme disease and plague in the United States was requested by Congressman Smith during hearings on Minor Use Pesticides. This information should be included in the testimony provided by William Hazeltine, representing the American Mosquito Control Association.

Sincerely,

Lucas G. Terracina
Interim Executive Director, AMCA

enclosures

FAX MESSAGE**DATE:** June 14, 1993

**MEDICAL ENTOMOLOGY-ECOLOGY BRANCH
DIVISION OF VECTOR-BORNE INFECTIOUS DISEASES
NATIONAL CENTER FOR INFECTIOUS DISEASES
CENTERS FOR DISEASE CONTROL AND PREVENTION**

**P.O. BOX 2087
FORT COLLINS, CO 80522 (USA)
PHONE (303)221-6477 - FAX (303)221-6476**

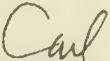
FROM: Dr. Carl Mitchell**FAX:** 916 534-9916**TO:** Dr. William Hazeltine**TELEPHONE:** 916-533-6038**LOCATION:** Butte Co. MAD**PAGES TO FOLLOW:** 3**MESSAGE:**

Bill, Here are case data for arboviruses, Lyme disease and plague. For information on other vector-borne diseases call the following in Atlanta.

Dr. Robert Kaiser 404-488-4060
(Malaria)

Dr. James Olson 404-639-1075
(Rocky Mountain Spotted Fever)

Regards.



Carl J. Mitchell, Sc.D.

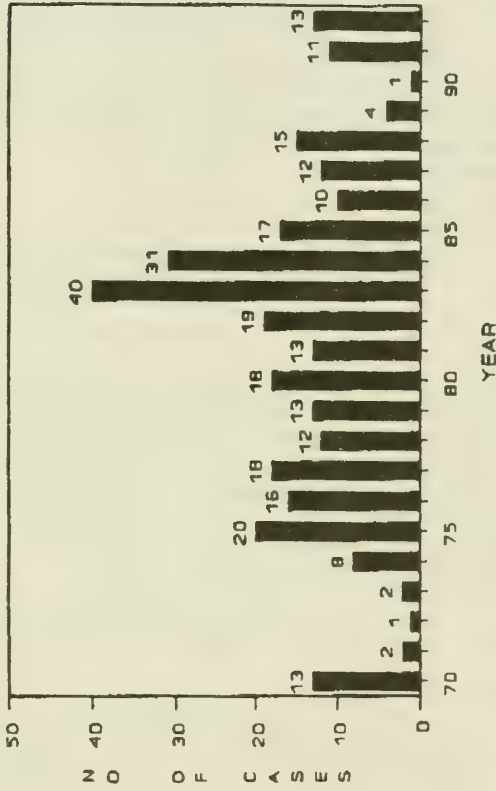
Reported Cases of Arboviral Encephalitis in the U.S.

Humans

Year	EEE	SLE	WEE	LAC	Total
70	2	15	4	89	110
71	4	57	11	58	130
72	0	13	8	46	67
73	7	5	4	75	91
74	4	74	2	30	110
75	3	1,815	133	160	2,111
76	0	379	1	47	427
77	1	132	41	65	239
78	5	26	3	109	143
79	3	32	3	139	177
80	8	125	0	49	182
81	0	15	19	91	125
82	12	34	9	130	185
83	14	19	7	64	104
84	5	33	2	89	129
85	0	21	1	68	90
86	1	43	7	64	115
87	3	17	41	87	148
88	1	0	0	42	43
89	9	34	0	65	108
90	5	240	0	61	306
91	11	78	1	41	131
92	2	14	0	29	45
Totals	100	3,221	297	1,698	5,316

Lyme Disease Surveillance Spreadsheet

STATE	1982	1983	1984	1985	1986	1987	1988	1989	1990	1991	1992	TOTAL	1992-93
ALABAMA	0	0	0	0	1	1	1	25	33	53	10	147	147
ALASKA	0	0	0	0	0	0	0	0	0	0	0	0	0
ARIZONA	0	0	0	0	0	0	0	0	0	0	0	0	0
ARKANSAS	0	0	0	0	0	0	0	0	0	0	0	0	0
CALIFORNIA	0	13	24	36	62	84	100	210	315	265	231	105	165
COLORADO	0	0	0	0	0	0	0	0	0	0	0	0	0
CONNECTICUT	35	73	63	639	0	212	362	354	344	1132	1705	6397	5319
DELAWARE	1	1	0	0	0	0	0	0	0	0	0	1	1
FLORIDA	0	0	0	0	0	0	0	0	0	0	0	0	0
GEORGIA	0	0	0	0	0	0	0	0	0	0	0	0	0
HAWAII	0	0	0	0	0	0	0	0	0	0	0	0	0
IDAHO	0	0	0	0	0	0	0	0	0	0	0	0	0
ILLINOIS	0	0	0	0	0	0	0	0	0	0	0	0	0
INDIANA	0	0	0	0	0	0	0	0	0	0	0	0	0
IOWA	0	0	0	0	0	0	0	0	0	0	0	0	0
KANSAS	0	0	0	0	0	0	0	0	0	0	0	0	0
KENTUCKY	0	0	0	0	0	0	0	0	0	0	0	0	0
LOUISIANA	0	0	0	0	0	0	0	0	0	0	0	0	0
MAINE	0	0	0	0	0	0	0	0	0	0	0	0	0
MARYLAND	0	0	0	0	0	0	0	0	0	0	0	0	0
MASSACHUSETTS	3	4	1	23	15	27	46	338	218	282	313	134	134
MICHIGAN	15	33	33	143	33	33	33	165	136	44	35	401	35
MINNESOTA	0	0	0	0	0	0	0	0	0	0	0	0	0
MISSISSIPPI	0	0	0	0	0	0	0	0	0	0	0	0	0
MISSOURI	0	0	0	0	0	0	0	0	0	0	0	0	0
MONTANA	0	0	0	0	0	0	0	0	0	0	0	0	0
NEBRASKA	0	0	0	0	0	0	0	0	0	0	0	0	0
NEVADA	0	0	0	0	0	0	0	0	0	0	0	0	0
NEW HAMPSHIRE	0	0	0	0	0	0	0	0	0	0	0	0	0
NEW JERSEY	53	70	155	175	219	257	500	680	1074	955	489	310	489
NEW MEXICO	0	0	0	0	0	0	0	0	0	0	0	0	0
NEW YORK	179	29	46	1335	482	877	2137	3224	3244	3544	3370	1995	470
NORTH CAROLINA	0	0	0	0	0	0	0	0	0	0	0	0	0
NORTH DAKOTA	0	0	0	0	0	0	0	0	0	0	0	0	0
OHIO	0	0	0	0	0	0	0	0	0	0	0	0	0
OKLAHOMA	0	0	0	0	0	0	0	0	0	0	0	0	0
OREGON	0	0	0	0	0	0	0	0	0	0	0	0	0
PENNSYLVANIA	2	0	5	25	33	35	306	624	553	718	1319	1455	1455
RHODE ISLAND	0	0	0	0	0	0	0	0	0	0	0	0	0
SOUTH CAROLINA	0	0	0	0	0	0	0	0	0	0	0	0	0
SOUTH DAKOTA	0	0	0	0	0	0	0	0	0	0	0	0	0
TENNESSEE	0	0	0	0	0	0	0	0	0	0	0	0	0
TEXAS	0	0	0	0	0	0	0	0	0	0	0	0	0
UTAH	0	0	0	0	0	0	0	0	0	0	0	0	0
Vermont	0	0	0	0	0	0	0	0	0	0	0	0	0
VIRGINIA	0	0	0	0	0	0	0	0	0	0	0	0	0
WASHINGTON	0	0	0	0	0	0	0	0	0	0	0	0	0
WEST VIRGINIA	0	0	0	0	0	0	0	0	0	0	0	0	0
WISCONSIN	58	59	136	255	312	318	346	763	337	454	525	1292	525
WYOMING	0	0	0	0	0	0	0	0	0	0	0	0	0
TOTAL	100	154	1510	2740	3187	2392	4882	8802	7943	9454	9637	40895	24899000
1992-93	0	0	0	0	0	0	0	0	0	0	0	0	0
1993-94	0	0	0	0	0	0	0	0	0	0	0	0	0
1994-95	0	0	0	0	0	0	0	0	0	0	0	0	0
1995-96	0	0	0	0	0	0	0	0	0	0	0	0	0
1996-97	0	0	0	0	0	0	0	0	0	0	0	0	0
1997-98	0	0	0	0	0	0	0	0	0	0	0	0	0
1998-99	0	0	0	0	0	0	0	0	0	0	0	0	0
1999-00	0	0	0	0	0	0	0	0	0	0	0	0	0
2000-01	0	0	0	0	0	0	0	0	0	0	0	0	0
2001-02	0	0	0	0	0	0	0	0	0	0	0	0	0
2002-03	0	0	0	0	0	0	0	0	0	0	0	0	0
2003-04	0	0	0	0	0	0	0	0	0	0	0	0	0
2004-05	0	0	0	0	0	0	0	0	0	0	0	0	0
2005-06	0	0	0	0	0	0	0	0	0	0	0	0	0
2006-07	0	0	0	0	0	0	0	0	0	0	0	0	0
2007-08	0	0	0	0	0	0	0	0	0	0	0	0	0
2008-09	0	0	0	0	0	0	0	0	0	0	0	0	0
2009-10	0	0	0	0	0	0	0	0	0	0	0	0	0
2010-11	0	0	0	0	0	0	0	0	0	0	0	0	0
2011-12	0	0	0	0	0	0	0	0	0	0	0	0	0
2012-13	0	0	0	0	0	0	0	0	0	0	0	0	0
2013-14	0	0	0	0	0	0	0	0	0	0	0	0	0
2014-15	0	0	0	0	0	0	0	0	0	0	0	0	0
2015-16	0	0	0	0	0	0	0	0	0	0	0	0	0
2016-17	0	0	0	0	0	0	0	0	0	0	0	0	0
2017-18	0	0	0	0	0	0	0	0	0	0	0	0	0
2018-19	0	0	0	0	0	0	0	0	0	0	0	0	0
2019-20	0	0	0	0	0	0	0	0	0	0	0	0	0
2020-21	0	0	0	0	0	0	0	0	0	0	0	0	0
2021-22	0	0	0	0	0	0	0	0	0	0	0	0	0
2022-23	0	0	0	0	0	0	0	0	0	0	0	0	0
2023-24	0	0	0	0	0	0	0	0	0	0	0	0	0
2024-25	0	0	0	0	0	0	0	0	0	0	0	0	0
2025-26	0	0	0	0	0	0	0	0	0	0	0	0	0
2026-27	0	0	0	0	0	0	0	0	0	0	0	0	0
2027-28	0	0	0	0	0	0	0	0	0	0	0	0	0
2028-29	0	0	0	0	0	0	0	0	0	0	0	0	0
2029-30	0	0	0	0	0	0	0	0	0	0	0	0	0
2030-31	0	0	0	0	0	0	0	0	0	0	0	0	0
2031-32	0	0	0	0	0	0	0	0	0	0	0	0	0
2032-33	0	0	0	0	0	0	0	0	0	0	0	0	0
2033-34	0	0	0	0	0	0	0	0	0	0	0	0	0
2034-35	0	0	0	0	0	0	0	0	0	0	0	0	0
2035-36	0	0	0	0	0	0	0	0	0	0	0	0	0
2036-37	0	0	0	0	0	0	0	0	0	0	0	0	0
2037-38	0	0	0	0	0	0	0	0	0	0	0	0	0
2038-39	0	0	0	0	0	0	0	0	0	0	0	0	0
2039-40	0	0	0	0	0	0	0	0	0	0	0	0	0
2040-41	0	0	0	0	0	0	0	0	0	0	0	0	0
2041-42	0	0	0	0	0	0	0	0	0	0	0	0	0
2042-43	0	0	0	0	0	0	0	0	0	0	0	0	0
2043-44	0	0	0	0	0	0	0	0	0	0	0	0	0
2044-45	0	0	0	0	0	0	0	0	0	0	0	0	0
2045-46	0	0	0	0	0	0	0	0	0	0	0	0	0
2046-47	0	0	0	0	0	0	0	0	0	0	0	0	0
2047-48	0	0	0	0	0	0	0	0	0	0	0	0	0
2048-49	0	0	0	0	0	0	0	0	0	0	0	0	0
2049-50	0	0	0	0	0	0	0	0	0	0	0	0	0
2050-51	0	0	0	0	0	0	0	0	0	0	0	0	0
2051-52	0	0	0	0	0	0	0	0	0	0	0	0	0
2052-53	0	0	0	0	0	0	0	0	0	0	0	0	0
2053-54	0	0	0	0	0	0	0	0	0	0	0	0	0
2054-55	0	0	0	0	0	0	0	0	0	0	0	0	0
2055-56	0	0	0	0	0	0	0	0	0	0	0	0	0
2056-57	0	0	0	0	0	0	0	0	0	0	0	0	0
2057-58	0	0	0	0	0	0	0	0	0	0	0	0	0
2058-59	0	0	0	0	0	0	0	0	0	0	0	0	0
2059-60	0	0	0	0	0	0	0	0	0	0	0	0	0
2060-61	0	0	0	0	0	0	0	0	0	0	0	0	0
2061-62	0	0	0	0	0	0	0	0	0	0	0	0	0
2062-63	0	0	0	0	0	0	0	0	0	0	0	0	0
2063-64	0	0	0	0	0	0	0	0	0	0	0	0	0
2064-65	0	0	0	0	0	0	0	0	0	0	0	0	0
2065-66	0	0	0	0	0	0	0	0	0	0	0	0	0
2066-67	0	0	0	0	0	0	0	0	0	0	0	0	0
2067-68	0	0	0										



**Figure 1: Reported Human Plague Cases
By Year - U.S.A., 1970-1992**

Mr. SMITH. Dr. Hazeltine, it seems to me that throughout all of this discussion we've paid a great deal of attention to risk. Everybody's talking about risk. Nobody's talking about the benefits of these programs, and if you have it in your testimony, I would like for you to supplement it with the benefits to humans as well as you have to the endangered species.

Mr. HAZELTINE. Well, we have tried to continually do this, and we thank you for that opportunity. As I understand, your request is to submit something about the benefit side?

Mr. SMITH. Exactly.

Mr. HAZELTINE. OK.

Mr. SMITH. Thank you.

To any of you—I guess Mr. Botts would be the logical person to ask this question. If H.R. 967 were passed, would we continue to need section 18?

Mr. BOTTS. Yes, sir.

Mr. SMITH. Why?

Mr. BOTTS. There's always going to be a lag time between identification of a new product and registration, and there are ongoing problems that develop continuously in crop production systems that may or may not be addressed by existing products that are registered. As those come up, the mechanism that's available through section 18 is appropriate.

Mr. SMITH. Well, it seems to me like section 18 kind of saved us from total disaster. Certainly in my area it has.

Mr. BOTTS. It has in Florida as well.

Mr. SMITH. Dr. Guest, were you involved through IR-4 in the hops and snap bean issue in the Northwest on Ronolan in particular?

Mr. GUEST. We have been involved with hops fairly extensively. I just recently had a list of hops projects that we have been working on actively or have recently concluded, and I think we are involved in about 16 different hops projects for pesticides. I would have to say that the hops industry is an industry that early on identified their needs, the reregistration liabilities, and came to IR-4, and we sat down and developed a program largely funded by that industry to develop data to either register or reregister new products. Early on we were interested in revising the definition of dried hops as a raw agricultural commodity, because I think it just makes a whole lot of sense.

Mr. SMITH. I understand that there has been a letter received by Senator Hatfield that has denied that alternative situation in that case, and I thank you for assisting what is practically a Pacific Northwest crop, with Oregon, Washington, and Idaho producing 39 percent of the world supply of hops—quite important, of course, to us, exporting 70 percent of the crop. What, in your mind, is an answer, since we've dropped, as you know, two useful chemicals recently, and the hop industry is in danger again, and if it's denied the alternative of being another type of crop, then we're back in the soup? Is there any hope in the future for an alternative chemical?

Mr. GUEST. There are a couple of alternatives on the horizon, a couple of which we're researching right now. To what extent they may or may not be affected by the Delaney situation, I'm not prepared to state at this moment. But I would be happy to provide

your office with this list of projects that we have been vigorously working on for the last several years.

Mr. SMITH. Yes. I appreciate that help. Thank you.

Thank you, Mr. Chairman.

Mr. STENHOLM. Mr. Dooley.

Mr. DOOLEY. I'd like to thank all of the panelists for their comments. In the hearing we had a couple days ago and following up with this one, I think a lot of us are becoming increasingly convinced that really the problem we face with minor use and availability is there are two factors here. There certainly is the one which pertains to the need to ensure that we can have some type of reregistration or registration process that allows these materials to be available, whether it's also providing financial incentives or doing what a lot of you folks have been trying to do in the IR-4. But I think what is becoming even more clear is that the minor use problem is going to continue unless we find some way to rationalize the risk analysis process that leads to the registration.

I know Congressman Smith and I spent quite a bit of time in the first panel talking about the methodology that is used by EPA now, which appears that nobody wants to say that it's a terrific system out there. Everybody complains about its faults, but they kind of almost always default, "Well, it's the best we have out there," and they're referring primarily to the maximum tolerated dose scenario, which a lot of us think does not give us an accurate depiction of the true risk that is being posed by many of these materials and certainly doesn't address the real benefits.

What I would be interested in is, I'm not convinced that it's the best system out there, and, Dr. Guest, I know that you have spent some time in Europe recently, and any of the other panelists—I know that a lot of Europeans are every bit as concerned about consumer safety and worker safety as we are in this country. Are they employing some other type of methodology that is providing for a more realistic depiction of the risk?

Mr. GUEST. Congressman Dooley, I don't profess to be an expert on what's going on in Germany. From my brief visit there, my impression was that they were seeking the same kinds of solutions that we're seeking here, but they don't seem to have a vantage of the cooperative nature of what we're doing here. The regulatory process, in my opinion, seemed to be much more fragmented, and there was clearly tension between the agricultural chemical industry, the registration branches of their Government, and certainly among the commodity producers, and I think they are searching. If we were to make a comparison, I would venture that probably we are in pretty good shape in this country. Not perfect by a long shot, but in pretty good shape.

Mr. DOOLEY. I guess it still gets back to the central issue that really what happens in the way we're doing our current testing and registration is that when you establish these certain thresholds, you have the allowable intake, which gets used up by all your major commodities. If we could get a more realistic assessment of that, these manufacturers would certainly be more willing to register these multiple commodities, a lot of them being minor uses.

Dr. Hazeltine, do you have a comment?

Mr. HAZELTINE. I'd like to step out of the role of representing the association and speak only as a scientist. Let me comment that as I view the situation, maximum tolerated dose is part of a win-win situation for people who want to eliminate chemicals as far as a useful tool. If a chemical is acutely toxic, it isn't going to cause cancer or be a problem in the long term. If it is a safe chemical, then the other alternative is to go to the maximum tolerated dose. If you can make the test animal sick long enough, in my view, you can have those animals produce all sorts of adverse effects, cancers and other things. As a consequence, I think that the maximum tolerated dose is an inept way to try and establish good toxicology.

Mr. DOOLEY. I was thinking about this the other day, and there are some real similarities even among humans. We find people who are chronic alcoholics who keep themselves in a state of physical sickness for a period of time, become susceptible to a lot of other diseases, and they die more frequently than other people, and it, again, seems like there is some analogy to this testing protocol that we've established.

What I was also interested in is some of the information that we're trying to gather and some of the data—and some of it is on the residue standards—is that there seems to be a need to have a greater coordination on adopting standard protocols that can allow the EPA and USDA to have a greater degree of confidence in some of the work that's done by various States, and we had a hearing last year where they said that some of the work that they were being mandated to carry out and trying to really gain a better understanding of the level of residues that are on some of our commodities and products was being hindered because there wasn't the standard protocols out there.

Secretary Brown, I'd be interested, in the State of New Jersey, are you working in a manner in which the standards that you're imposing and the information that you're requiring of registrants is compatible and identical to that that the EPA is requiring?

Mr. BROWN. Congressman, in the State of New Jersey, the department of agriculture does not have the responsibility of regulating pesticide use. It's under the department of environmental protection and energy, and certainly they work very closely with the college of agriculture, but we have no responsibility whatsoever in that.

Mr. DOOLEY. So you're not aware that the standards in the protocols are the same as what the EPA would be requiring?

Mr. BROWN. I would say that they probably are, but I would not specifically tell you yes, because I don't know.

Mr. DOOLEY. Dr. Hazeltine, you mentioned in your testimony the need to get standards for all 50 States. Apparently, you think there's a problem here of some nature.

Mr. HAZELTINE. Well, let me point out an example. I realize that time has run, but there was an example of a chemical called pyrethrin. It's an organic extract. The organic gardeners love it. It works in extremely low doses. I've done some calculations on this, and the manufacturers have been told that if they want a label claim for the use of this chemical over the rice crop, they will have to do something like 1.25 million dollars' worth of research.

I've done calculations based on the field use dose, and the conclusion that I've come to is that with a normal yield of rice crop, if everything we applied were to get onto that seed, it would be only about double what is now allowed as a residue for rice seed that is treated in storage to prevent the weevils and the moths from eating up that crop. We're told by the ag engineers we're lucky to get 10 percent of the applied dose to the target, so that would be seventh-tenths of 1 part per million, nowhere near the tolerance that's established.

Also, rice is in the boot when we treat it usually. If it's in the head, it's surrounded with the hull, and as a consequence, it seems to us that the requirements, the institutionalization of the risk factors in many of these things, has gone to excess and that there needs to be a measure of common sense introduced on the benefits side for EPA.

Mr. GUEST. Mr. Congressman, may I take just a minute to add that one proposal that's before EPA right now that's been worked on by the agricultural chemicals industry and IR-4 is a plan to develop standardized testing procedures, geographical data requirements for various crops from major-major to minor-minor, and it would identify locations where testing was needed, residue sampling was needed. If such a plan is finally approved by EPA, it would be a major step forward to a more uniform testing program and I think would be a major step in streamlining the whole process.

Mr. DOOLEY. I thank you for that information, Dr. Guest, and I'd be interested in following up with you to see if there's something we can do to help in terms of facilitating that adoption.

Mr. STENHOLM. Ms. Lambert.

Ms. LAMBERT. Mr. Chairman, I appreciate the opportunity to hear the testimony of these gentlemen.

In my district we deal mostly on the traditional agricultural level. We are encouraging more of the minor crop involvement by our farmers, so I am very interested in hearing this testimony, especially on the minor crops and the biocertified.

My question is for Mr. Maslyn. How many reregistrations of the minor-use pesticides are a result of the economic factors?

Mr. MASLYN. I'm not sure, Congresswoman, exactly how many of them are attributed to economic reasons. It is a major factor. If you talk to the registrants, it is a factor. It is believed to be the majority of the cases.

Mr. GUEST. May I comment on that? I mentioned our extensive surveys that we did in 1989 in connection with reregistration and development of our strategic plan. At that time, we estimated, based on our surveys with the agricultural chemical industry, with growers, that there would be about 1,000 minor-use reregistrations that would not be defended by industry that were needed by the agricultural community. We have not yet seen that 1,000. We have probably worked on a couple hundred and maybe have several hundred more, maybe about one-half of that 1,000 right now, but I don't think we've seen the landslide yet of reregistration cancellations coming down the pike. I think that's still to come, and I think it will occur, but our initial estimate was about 1,000 that we would need to defend.

Ms. LAMBERT. So there has not been an accurate polling or any kind of idea of what might happen.

My other concern was kind of touched on, I guess, and I don't know if there's any collaboration with those of you that do the investigation of insecticide and herbicides. In my district, we have the National Rice Germ Plasm Center, and they deal basically with actual built-in plant toxins that are emitted from the plant. Is there any work done in correlation with some of the issues that you all deal with as far as herbicides are concerned along with studies where the actual toxins in the plants are the preventative measure or inhibit the growth of weeds around the plants? Do you all ever do any of that in collaboration?

Mr. GUEST. No.

Mr. BOTTS. For specific commodities where things show up typically as a result of cultural practices that are taking place—for example, from personal experience, I worked for a large grower that grew both celery and lettuce, and after harvest of the celery crop where the trash rows were piled, they planted lettuce and saw a severe decrease in stand of lettuce in the trash row piles from where they had field harvested the celery. As a result of that observation, an attempt was made to identify the specific compound that was causing the allelopathy, which is common in desert plants and other places. There have been some compounds identified that are naturally produced by celery, which may in turn be looked at for herbicidal properties in the future.

But those are the types of projects that get into the biotech-type issues and those kind of things that take a tremendous amount of time and a lot of effort by multiple people to get it resolved, and it's—

Ms. LAMBERT. But not necessarily the development of strains. I know, for instance, in rice what we have is that there are certain strains of rice that actually produce toxins that inhibit the growth of weeds around them, and it's fascinating to watch. You can actually see there's a big circle around the rice where there are no weeds growing. So I just didn't know if there were other ways that you all worked in tandem with that kind of research.

Is there any way that we can estimate—and I guess there's not, if you don't have any idea of what cancellations would actually happen—the economic impact that the proposed cancellations would have on minor crop producers?

Mr. MASLYN. We've estimated the value of minor crops to be in the \$30-billion range. As Dr. Guest said, we're still trying to identify which of those products are not going to be supported in the final analysis, and when we know that, we'll be able to better guesstimate what the impact might be.

Ms. LAMBERT. This is just for my own information. In my district last week, on my district work period, strawberries were great in Arkansas, and so were the mosquitoes, for that matter. But I did have several of my strawberry growers ask me if they were going to have to require their pick-your-own to wear gloves in the instance of some of the—I know we're talking about the malkeine, some of those. Is that necessary, in your opinion?

Is this OK for me to ask? [Laughter.]

Mr. STENHOLM. Surely.

Mr. BOTTS. If there's a label requirement that says anybody who goes in the field has to wear gloves during a certain period of time, yes, it's necessary, or else the person who made the application could be cited and fined. From a health standpoint, that's a whole different question and is almost case-specific, depending on the chemical that you're looking at.

Ms. LAMBERT. OK.

Thank you, Mr. Chairman.

Mr. STENHOLM. Thank you.

We've got a vote on right now. Just one question I wanted to ask you. Several of you, if not all of you, have mentioned the need for additional research, additional funding in the areas of concern, and we all concur to that. My question to you is, if it were your money, you were writing a personal check out of your own account for whatever amount of money that we're talking about is necessary, would you write the check and give it to the system as it is currently constituted, without requiring changes in the manner in which we administer the various programs around the research and development? Would you write the check, give it to the bureaucracy, without demanding changes? What I'm saying is, is our current system adequate if it only had more money, in your opinion?

Mr. GUEST. May I speak from the standpoint of IR-4? Of course, I would have to say yes to the funding issue, but equally important to more money for our program is we're on a year-to-year budget, which makes it very difficult to operate our program. It's very difficult to employ project coordinators, technicians in laboratories, and so forth. As much as money, we need to be able to say that we have money for a period of time so we can develop field research centers, so we can bring laboratory technicians in and guarantee them a job for at least a couple of years.

We need some degree of permanence of money. Not a guaranteed check forever, but on a year-to-year basis it's very difficult to run our kind of program, and it does detract from our efficiency.

Mr. STENHOLM. Well, then, really the answer to my question from you is no, that there needs to be some changes in the manner in which it's administered is what you're saying also.

Would anyone else briefly comment?

Mr. HAZELTINE. In the public health area, our constituents in many States pay a special assessment. They know what it costs for mosquito control programs, and the word that we have from our constituents is, "Be efficient. If it's necessary, do it. If it is not necessary, don't spend the money." The issue of efficiency, I think, is one of the major concerns that we have, that we want good value for dollars spent, and our people do pay for good programs.

Mr. STENHOLM. Another, not a question as much as a comment. Secretary Brown, you mentioned that many economists and other scientists have clearly demonstrated that it is impossible to achieve a zero-risk society. Each of you have testified to different degrees regarding that, and if there's one goal that I have for this committee in our entire effort, it's to begin to dispel the myth that this committee or this Government can create something that God himself did not create for society. One of the political problems we con-

tinue to have to deal with is the impression that we can create a perfectly safe food supply. It cannot be done.

This is something that has to be done. Somehow, some way, we have to reach the general public and dispel the myth or prove it.

This is the frustrating thing about the political side of this question, but your testimony and others will certainly move us down that line, and this is one of these foundation building blocks of this process that I think we have to get over. We have to get over that there is no benefit to be achieved from some of the products that are often attacked and that we have to look at a balanced assessment of the various things that we're talking about if we're going to ever get from point A to point B.

I thank you for being here. I would discharge this subcommittee. We have a vote, two votes, in fact, so I will briefly recess. We will recess for at least 15 minutes, so if anyone needs to leave, and then we'll call the second panel no earlier than 12:15 p.m. We'll be in recess until that time.

[Recess taken.]

Mr. STENHOLM. We will reconvene the hearing.

We'll call on our first witness, Dr. George Templeton, professor of plant pathology, department of plant pathology, University of Arkansas.

Dr. Templeton.

**STATEMENT OF GEORGE E. TEMPLETON, DISTINGUISHED
PROFESSOR, DEPARTMENT OF PLANT PATHOLOGY, COL-
LEGE OF AGRICULTURE AND HOME ECONOMICS, UNIVER-
SITY OF ARKANSAS**

Mr. TEMPLETON. Thank you, Mr. Chairman. I'm very honored to have this opportunity to make these comments to the committee, and I'm grateful for the opportunity. I have submitted some written testimony, which I'll be happy to answer questions about, but with your permission Mr. Chairman, I'll speak mainly from the outline in my summary.

I have been working on biological control of weeds with plant diseases, diseases caused by fungi, for 24 years and was part of a pioneering group at Arkansas that got one of the first biological herbicides registered by EPA. We feel like there's a great opportunity here if we could set aside registration and economic problems.

First of all, let me just say that we have only two biological herbicides available in the United States at this time: One in Florida for control of the strangler vine in citrus that was registered by Abbot Laboratories in 1981, a project of the Florida Department of Agriculture and the University of Florida. A second from our project at Arkansas was for control of the northern jointvetch weed in Arkansas rice and soybean fields, and that project required 13 years to complete. We started in 1969, and it was on the market in 1982.

I estimate that its cost was about \$2 million, and the market size of that product is so small that it will take 56 years to reach the break-even point. So you see we have an economic situation that is not very interesting to industry, and I'm sure the gentlemen that follow will point that out. Actually, the amount of biologicals used is trivial. For example, in rice in Arkansas we use 150 pounds of

biological each year. On the other hand we use 7 million pounds of chemical active ingredient for weed control in Arkansas rice each year. Biologicals are just not a very large component of our pest management in rice. Our product is safe, because it is highly specific, but of course, that accounts for its economic disadvantage as is true of most biologicals.

Biologicals are not attractive to the large chemical companies. Some of the smaller companies are more interested in them but they would certainly be more attractive to venture capital companies or small enterprises if the registration cost for biologicals could be reduced.

Our project was the first on the use of an indigenous organism as a bioherbicide. It was already present there in the Arkansas rice fields. We isolate the organism in pure culture, increase it in fermentation tanks, and then applied it in the rice from which it had come. It took a team of Federal and State scientists, with the cooperation of industry—the Upjohn Pharmaceutical Company—to get it on the market. Upjohn would not provide financial support for us, because they realized the low market potential and the costs of registration, particularly since there were no guidelines at that time for registration of biologicals. We were pioneering in the area of registration, and, it took us 9 years.

Prior to registration efforts, I satisfied myself in 4 years, the first 4 years before we ever went to EPA, that we had safe product using professional standards that are used by all plant pathologists before they use fungi in pure culture and test them in the field. Consequently, it is my recommendation that the registration process simply require that bioherbicides be exempt from FIFRA. These types of organisms should only need to satisfy professional standards, and that professional standards be assured by peer review of projects. That's the process that we used with the product COLLEGO®. We have been using COLLEGO® in Arkansas rice fields for 10 years without harm to people or the environment or the ground water or food supply or anything.

In my experience, I have had a very good working relationship with EPA. They were very helpful in trying to establish what should be required. They have substantially reduced the amount of data required for registration of biologicals, but there's still more required than is scientifically credible. Therefore, again, I would recommend that indigenous bioherbicides be exempted from Federal regulation under FIFRA.

Another problem that has developed since then has been the coordinated framework so that all the agencies of the Government will be coordinating regulations. That has caused some agencies to require more data now than was required in 1982. For example, the USDA-APHIS was not interested in regulation of our product at that time. They said, "If it satisfies EPA, then it will be OK with us." But now we have indications that APHIS wants to also require applications and permits for field tests, before we move these pathogens of weeds interstate, even though they have been demonstrated host-specific for certain weeds.

Finally Mr. Chairman, one of the points that I wanted to mention is the labels that EPA required for COLLEGO®. They may be seen in figure's 2A and 2B. This is a label for the spore rehydrating

agent of this product, and it is corn syrup. Yet they require us, because it is used as a pesticide, to put on the label, "Keep out of the reach of children. Caution: See side panel for precautionary statements," and then on the side panel you've got pesticide disposal and container disposal requirements just as if it were a hazardous chemical.

That gives the public the impression that we are dealing with something that's pretty hazardous, yet these organisms aren't hazardous to anything but the weed. They're highly specific for that weed. The same thing is even worse on the package containing the organism, figure 2B. We must put, "Keep out of the reach of children. Caution: Statement of practical treatment" and so forth. Those things give the wrong impression that biologicals are risky.

Finally, I would like to illustrate just how ridiculous some of the regulation can be. If you look on about page 11, there's one of the forms required to move a human pathogen interstate. I can sign this statement that I will be responsible—"I will hereby assume all risk and responsibilities in connection with the receipt, handling, storage, and use of this material." If I sign that, I can get a culture of *Bacillus anthracis* from the American Type Culture Collection in Rockville, Maryland, in about a week. On the other hand, if I want to get a culture of a fungus from a weed in Colorado that kills nothing but a weed and test it in Arkansas, it takes 2 years with the permit illustrated in figure 1B, plus an environmental impact assessment, and 2 years of negotiation to move that weed pathogen from Colorado to Arkansas.

Now, surely to goodness, if I can be trusted to handle a human pathogen that's used in biological warfare agents simply by signing my name, I ought to be able to move from Colorado to Arkansas a pathogen that kills nothing but a weed just as easily.

So, in conclusion, my recommendation is that requirements for registration of biologicals be dropped. I don't think we'll have any major impact on the reduction of chemicals with biologicals until we get some relief from a regulatory standpoint as well as a lot of additional public research funds.

Thank you.

[The prepared statement of Mr. Templeton appears at the conclusion of the hearing.]

Mr. DOOLEY [assuming chair]. Thank you, Dr. Templeton.

I apologize for the fact that we have another vote going on right now. The chairman will be back very shortly, but I think we'll continue with our oral statements, as we already have the written statements.

At this time, I'd like to go to Mr. Jim Wylie, who is the president and CEO of EcoScience.

Mr. Wylie.

STATEMENT OF JAMES A. WYLIE, JR., PRESIDENT AND CHIEF EXECUTIVE OFFICER, ECOSCIENCE CORP.

Mr. WYLIE. Good afternoon, Congressman Dooley. I appreciate the opportunity to present our oral remarks in front of the Subcommittee on Department Operations and Nutrition and other interested parties.

I am president and CEO of EcoScience Corporation, a company that has grown from 4 employees to over 131 over the last 4 years. We're a publicly traded emerging growth company focused on developing and commercializing safe and cost-effective natural pest control products—biopesticides—as alternatives to conventional chemical pesticides. These biopesticides under development by EcoScience will find their way into sensitive-use environments in homes, schools, hospitals, restaurants, used to improve the quality of fruit by protecting fruit and vegetables from disease, among a broad range of other applications.

EcoScience biopesticides have several distinct advantages over chemical pesticides: They are naturally occurring microorganisms, they are not genetically modified, they are derived from the environment, and they're compatible with the environment.

As chief executive officer of a small public company in the field of biopesticides, I am growing increasingly concerned that the future of our industry segment is in serious jeopardy. Attracting and, most importantly, keeping investor support is critical to the viability of our industry. Today a handful of firms like EcoScience rely heavily on public markets to access funding to support basic research, new product commercialization, and manufacturing. Government regulatory timeframes create uncertainty and severely impact our ability to attract the additional capital necessary to develop new and safer biopesticide products. This uncertainty is so great that large numbers of potential investors are afraid to invest in our growth industry. In short, there is a conflict between the viability of our industry segment and the EPA's regulatory process.

My purpose for being here today is not to criticize EPA, which has dedicated personnel doing an enormous job under very difficult constraints, but rather to make you aware of the issues facing this industry's emerging new businesses. Our goal is that together the biopesticide industry and EPA can seek, develop, and implement solutions to enhance the regulatory process while, at the same time, improving public health and environmental quality.

Approximately 10 years ago the EPA identified the field of microbial agents as a potential source of products that can be safer to humans and the environment. Further, EPA recognized the inherent safety of microbials when it established subdivision M guidelines providing for microbial product registration within 1 year. Unfortunately, while these guidelines provide an acceptable procedural framework to accelerate registration, EPA has not been able to effectively implement this policy. Consequently, although testing requirements for microbial agents are significantly less than those for chemical pesticides, actual product review times remain excessively long and, worse, unpredictable.

Although the large multinational pesticide companies are aggressively pursuing new generations of safer chemical pesticides for large agricultural markets, they are not focused on the development and commercialization of naturally occurring microbial pest control agents. Unless a way can be found to accelerate and predict the registration timeframe, companies like ours will find it increasingly difficult to access the public markets for financing. Without the availability of equity funding, companies like EcoScience will

disappear, microbial-based biological pesticide research will be severely hampered and innovation stifled.

A typical microbial registration package is relatively quite small when compared to the volumes of data filed on chemical products. Therefore, the time required for microbial review should be shorter. Despite the 1-year guideline and fewer and less complex studies that are required, it is not unusual for the registration process for microbial products to take as much as 2 years or more to complete.

EPA has spent considerable time over the last 2 years considering measures to improve the registration process for reduced risk pesticides. This work is extremely important, but our company believes that the extensive regulatory framework is already in place to provide acceleration of biological product registration under the previously mentioned subdivision M guidelines.

We have one other deep concern. This concern is related to the agency's overly restrictive policy on labeling claims for some biological pesticides. Today, firms like EcoScience are prohibited from stating that our products are natural or naturally occurring organisms. We are not even permitted to state that the product contains no chemical pesticide. The agency's position is that these words imply safety claims. We disagree. The public has the right to know that a product is made from naturally occurring substances. They certainly should have the right to know that a product contains no chemicals. EPA's current position is actually a deterrent to stimulating consumer demand for more environmentally compatible, safer alternatives to conventional chemical pesticides.

In summary, I believe the issues of registration timeframe and predictability can be alleviated by a focused EPA leadership and a dedicated management commitment to registering environmentally compatible products. EcoScience recommends the following steps for consideration. Importantly, all of these can be accomplished within FIFRA and, as pointed out earlier, during this session of Congress.

First and foremost, we believe this committee should urge the EPA to place a high priority on biopesticide registration by effectively implementing subdivision M guidelines. Second, EPA should create a separate branch within the Office of Pesticide Programs to implement and manage the registration of microbial, biochemical, and plant pesticide products. Third, the proposed branch should be staffed with a dedicated team of scientifically knowledgeable reviewers focused solely on biopesticides. Fourth, biological pesticides should be excluded from the reduced-risk pesticide policy currently under development at EPA to ensure that biopesticides receive focused review and accelerated registration. Fifth, data review and product registration should be accomplished within a 6-month time frame. Final registration timeframes must be met and be predictable. Sixth, naturally occurring, nongenetically modified biopesticide registrants should be allowed no make the following label claims: "natural" or "naturally occurring," "contains no chemical pesticide."

EcoScience stands ready to work closely with the EPA and your committee to seek effective solutions to the complex problems of pesticide registration.

Thank you for the opportunity to express our views.

[The prepared statement of Mr. Wylie appears at the conclusion of the hearing.]

Mr. DOOLEY. Thank you, Mr. Wylie.

We'll now move on to Dr. James Davis, who's vice president of research and development for Crop Genetics International.

Dr. Davis.

STATEMENT OF JAMES H. DAVIS, VICE PRESIDENT, RESEARCH AND DEVELOPMENT, CROP GENETICS INTERNATIONAL CORP., ON BEHALF OF THE INDUSTRIAL BIOTECHNOLOGY ASSOCIATION

Mr. DAVIS. Thank you. I am Jim Davis, vice president of research and development at Crop Genetics. Crop Genetics is engaged in the development of new approaches to biological pest control, including the use of both genetically engineered and naturally occurring microorganisms. I am here today representing the member companies of the Industrial Biotechnology Association, and on behalf of the association, I would like to thank this subcommittee for inviting us to present our perspective on current pesticide registration issues.

IBA represents 157 large and small companies engaged in all forms of biotechnology R&D and manufacturing, including both dedicated biotechnology companies formed within the last 15 years as well as large multinational interests. Collectively, IBA member companies account for greater than 90 percent of the sales of microbial pesticides in the United States. Member companies are actively developing new biological solutions to crop protection, and many of these products are likely to fall under the coverage of FIFRA.

Since 1988, 17 new microbial active ingredients have been registered by EPA, and these products account for over one-half of the currently registered microbials. IBA anticipates that microbial products, including transgenic plants and microbial pesticides, will account for more than one-half of the new active ingredients submitted to EPA for registration over the next several years. These biological approaches are expected to play an increasing role in integrated pest management and improving the environmental safety of American agriculture.

Prompt registration of these biologicals is essential for ensuring the success of these products, and improving the registration procedures will expand the choice of pest control approaches for farmers, nurserymen, and foresters throughout the country.

Over 10 years ago EPA recognized that biological pesticides pose far fewer risks to human health and the environment. Traditional data requirements for chemical pesticides were in many cases not applicable to biologicals, so EPA's technical staff designed subdivision M data guidelines for biorational pesticides in recognition of this fact. Under these guidelines, the data required for biologicals are significantly less than that required for chemically derived pesticides. The guidelines include a three tiered approach, and no biological pesticide registered has ever had to go beyond tier 1 testing.

The central issue facing EPA and the industry is how to expedite the data review and the registration of these biological pesticides. IBA believes that registration product reviews should be completed

within 6 months of data submission. Now, EPA has taken steps over the past years to facilitate the registration process for biologicals. Two product review teams have been dedicated to the review and registration of these products. Unfortunately, product reviews have been delayed because scientific branches within OPP must deal with both chemical and biological products. The data packages for chemical products are often more complex, and the reviewers end up spending more time on these products, thus slowing down the review process for biological products. Moreover, many reviewers are often sidetracked into reregistration issues that prevent them from reviewing these new reduced-risk pesticides.

EPA's commitment to registering reduced-risk pesticides must include a reexamination of management practices as well as a commitment of adequate resources to the product review process. IBA believes that this can best be accomplished by the establishment of a separate branch within OPP's registration division to handle the review of biological products. With a dedicated team of reviewers whose primary responsibility is review of registration data for these biologicals, EPA will be able to facilitate markedly the registration process and handle the increasing number of biological submissions. EPA already has the expertise within OPP to staff such a division.

IBA believes the single most important step that EPA can take toward encouraging reduced-risk pesticides is to implement management changes that will speed up the registration process for biological approaches to pest control. With the establishment of a separate biologicals branch and a commitment to prompt review, we believe these products can be, and should be, reviewed within the 6-month timeframe. We've communicated our views to EPA, and our organization plans to meet with the Agency shortly to discuss implementation of these proposed changes.

Thank you.

[The prepared statement of Mr. Davis appears at the conclusion of the hearing.]

Mr. STENHOLM [resuming chair]. Dr. Caulder.

**STATEMENT OF JERRY CAULDER, PRESIDENT AND CHIEF
EXECUTIVE OFFICER, MYCOGEN CORP.**

Mr. CAULDER. Thank you. Let me begin by thanking you, Mr. Chairman, and all the members of the subcommittee for inviting me to testify on EPA's registration process for alternative pest control agents. I ask that my full statement be entered into the record, and I will provide the highlights—at least, highlights as I perceive them.

I am Jerry Caulder, president and CEO of Mycogen Corporation, a diversified agricultural biotechnology company. We develop and market environmentally compatible, effective biopesticides to control pests. We also improve crop varieties to increase food production and make them resistant to pests. Since Mycogen was the first company to receive EPA approval for a genetically engineered biopesticide, I'd like to describe our experience with EPA's registration process.

As background, the registered Mycogen products contain a naturally occurring pest toxin from the *Bacillus thuringiensis* bac-

terium. The toxin is inserted into another kind of bacterium, which is then killed, stabilizing the toxin within its cell walls. Farmers find the encapsulated active ingredient acts twice as long as traditional Bt's in the field, therefore applying less total chemical.

Mycogen has several EPA-approved products; however, we're not the only ones. Many other biotech and chemical companies have invested heavily in research to find alternative pest control agents. Biological approaches to pest control, including the use of microbial pesticides and transgenic plants, are expected to play an increasing role in integrated pest management. Improving registration procedures for these agents will expand the choice of new pest control approaches for farmers, nurserymen, foresters, and even avid weekend horticulturists worldwide, with safer products.

To understand the registration process and my recommended changes, I will briefly discuss alternative pesticides in a broader context. I own a farm in Missouri and grew up on a farm in Missouri and began my career developing and marketing chemical-based pesticides. At the time, these production protection agents were perceived as radical, revolutionary tools that could indeed revolutionize agriculture, as they did.

Agricultural practices, however, have changed, and consequently the American farmer is viewed now as the most productive and efficient farmer in the world, but some of the chemical pesticides have already lost their effectiveness as insects have developed resistance to them, and the list is growing. Currently, over 500 commercial insects are resistant to chemicals. Others have left residues in food and ground water, which, again, have raised public concern about the safety of pesticides.

Although chemical pesticides are an important tool and will be needed well into the next century, both traditional chemical companies and biotech companies are committed to finding alternatives to replace noxious products that safely and effectively control chemical-resistant pests. A wide array of new products have been developed. Many have been tested in the field. Most are stalled at the EPA, awaiting registration. The prolonged delay before commercialization troubles growers, investors, and executives like myself who have to manage these businesses. While companies await EPA approval, farmers and, consequently, the public are denied an array of effective alternatives to chemical pesticides.

I was reviewing some testimony you had earlier in the week by Victor Kimm, the Acting Assistant Administrator of the EPA, and I'd like to quote. He says, "EPA is committed to encouraging the development and use of environmentally accepted biological pesticides as alternatives to more toxic and persistent conventional chemical pesticides." I appreciate that statement being made, but I first heard it 8 or 9 years ago, and absolutely nothing has been done about it. It sounds good, it sounds like the right thing to say, and I'm sure it's certainly politically correct, but without action, it doesn't help us very much.

Just take Mycogen as an example. We began research 8 or 9 years ago to develop an effective biopesticide for the control of the diamondback moth on vegetable crops, because the pest has developed resistance to all of the synthetic chemical pesticides. These are minor crops, I might add also, and if you look at what compa-

nies like Mycogen are doing, we're concentrating more on developing products for minor crops than a lot of the major crops, which fits very well with the committee that testified before.

Despite the fact that the toxin in MVP, which is the trade name for our product, is highly specific to moths, has no effect on beneficial insects, no effect on mammals, birds, fish, or the environment, it took the EPA 2 years to grant Mycogen's approval for sale. Two years doesn't seem particularly long, but before that, just in order to test it, it took us 16 months to get a permit called an experimental use permit to test the product. So if you look at the statements by Victor Kimm it takes months to register these products, that has certainly not been my experience.

In early 1991, with final approval pending, the EPA decided that the application would be singled out for review by another office in the Agency, of which we could find no reason for it. That review kept us effectively out of the market for 1991. A lot of the people in registration aren't sensitive to the fact that a registration that gets cleared in April or May may get you in the market that year, but if it's cleared in June, you miss an entire year of sales. They're not sensitive to the fact that agriculture is a seasonal business.

The decision to have this dual review, in my opinion, was both a waste of money and highly inefficient. Mycogen complied totally with all requests for data and resubmitted duplicates of reports that were lost by the Agency. In return, we had expected efficient, effective, and timely review of our application. EPA's registration process dragged on, turned in circles, and ultimately failed to provide timely registration for us.

What barriers can be removed to make the regulatory process more responsive and effective for alternative pest control agents? To ensure that reduced-risk pesticides become available to the farmer without undue delay and that they are used widely and appropriately by farmers, I think EPA's Office of Pesticide Programs should do the following things: One, and you've heard it from the other people here, designate a specific unit of qualified scientific reviewers strictly dedicated to the overall review of biological pesticides, from screening of applications to approval—cradle to grave, so to speak; two, streamline the review process for alternative pesticide control agents that set mandatory deadlines for the review of and response to applications for field testing, registration, and amendment to the registration of these products. We in small companies can deal with expensive registration, we can deal with long registration, but what we can't deal with is uncertain registration. So we need to have a mechanism by which we can deal with some certainty in our planning.

The next thing I would suggest is couple an old chemical that's under special review and may be banned with an application of an alternative pesticide. Stated simply, if you're going to take a pesticide that's useful to the farmer off the marketplace and there are viable alternatives, couple those together so they would go through at the same time, and our farmers wouldn't be left in a lurch without a product that was effective on the problems that they were using it for.

Next, allow reduced-risk pesticides to declare factual information about their safety and environmental compatibility on the label or

in advertising. Again, I quote from Victor Kimm's testimony: "The EPA has set a goal of promoting safer methods of pest control." I've been hearing that, again, for a long time, and I would continue to quote, saying, "The agency plans to improve the informational content of pesticide labels and to develop other educational media—for example, pesticide fact sheets and training programs to permit more informed choices by the user and other affected parties. In addition, the Agency is considering allowing certain comparative safety claims in labeling and advertising materials." We need that, but, again, I've been hearing that for 7 or 8 years, and no action gets taken on it.

As Mr. Wylie at EcoScience pointed out, one of the most important things that we have in getting our products in the market is that they are different from chemical pesticides.

The next thing is, in cooperation with USDA's Extension program, provide education to the potential users about the benefits and proper usage of reduced-risk pesticides to avoid resistance problems. And, last, exempt users of registered alternative pest control agents from certain requirements for the purchase, storage, application, and disposal that are applied primarily to synthetic chemical pesticides. Dr. Templeton talked about that earlier, that some of these rules made for chemical pesticides just do not fit biologicals.

Congress needs to realign EPA's priorities to assure that farmers will have available new pesticides when they lose chemicals denied registrations and reregistrations. The U.S. ninth circuit court of appeals' *Les v. Reilly* decision on the Delaney clause, in my opinion, has elevated the urgency for this change.

In summary, EPA's current registration process for biologicals is inefficient, costly, and unduly protracted. The current system is designed purely and simply for chemicals and is not appropriate for biologicals in most cases, which pose no toxicity to humans, mammals, birds, or freshwater fish. If EPA used the scientific personnel and a review timetable that are appropriate to reduced-risk pesticides, the Agency could free many resources unnecessarily used under the existing registration process.

Large and small companies, including Mycogen, have invested heavily in research and development to provide the American farmer effective alternatives that are environmentally compatible and safe for farmworkers, animals, and fish. For small companies like Mycogen, investors do get restless. The availability of funds dries up rather quickly. We know exactly when our moneys run out. We know what we're trying to accomplish, and we think the regulatory process should help us rather than hinder us.

Thank you very much.

[The prepared statement of Mr. Caulder appears at the conclusion of the hearing.]

Mr. STENHOLM. Thank you.

Mr. Dooley.

Mr. DOOLEY. Dr. Caulder, I don't quite understand a point that you were making about the dual review and eliminating it. What process currently is in place?

Mr. CAULDER. Well, what happened to us specifically was that we got reviewed by TSCA, the Toxic Substance Act, with no basis

for that. It was purely an arbitrary decision. Our product is a pesticide. It's not an industrial molecule, should not have been reviewed by TSCA, but for some reason still unknown to us, it was kicked over to TSCA under the EPA. The FIFRA reviewed it, and then for some reason it got reviewed through TSCA, and to this day I have not been able to find out why.

Mr. DOOLEY. And that's a decision that EPA has the authority to make independently?

Mr. CAULDER. Obviously, because they did it. If you look at it from a—do they have the statutory authority to do it? No. Pesticides are reviewed under FIFRA. They're not reviewed under TSCA. We found it easier to comply than to resist, and unfortunately that happens a lot.

Mr. DOOLEY. Obviously, you issued concerns in this regard. What was the formal response from EPA. Did you request information on that decision?

Mr. CAULDER. Nothing formally, because there was really no basis for it. Informally, they just thought that they should do it.

Mr. DOOLEY. I guess also on a related issue, I think, Dr. Davis, it sounds like there is a lot of common ground between what all of you are advocating in terms of developing a separate branch that can be totally focused on some of these new alternatives. You mentioned that you felt that the Office of Pesticide Programs in EPA already has the authority to set up this separate branch. Is that correct?

Mr. DAVIS. Absolutely. They have the authority, and not only do they have the authority, but they have the personnel that are trained in the areas that they could use to establish that branch today. It's not like they have to go out and hire new people. They have people who deal with biologicals, who understand the biologicals. Unfortunately, a large percentage of the time of those people is spent on doing chemical pesticides, and they can't focus on the areas where in fact they have the expertise. So if we could put them all into one branch, which EPA has the authority to do, then the biological reviews could be done very quickly, because they'd be done by people who understand what biologicals are all about.

Mr. DOOLEY. Under the present system, when any of your firms have a material they want to have registered, what type of fees are you assessed in order to pay for this registration?

Mr. DAVIS. Well, in the case of my own company, we're a small enough company that we were able to get waivers of any fees.

Mr. CAULDER. The same situation. The payment of fees isn't the problem. It's just the time and the protracted amount of time that it takes to get registration.

Mr. DAVIS. I think one of the points that Dr. Caulder made is very important. It is not the money involved in a registration that bothers us as much as the time involved in a registration.

Mr. DOOLEY. The time and uncertainty.

Mr. DAVIS. Yes.

Mr. WYLIE. The unpredictability is impossible for us to deal with from an investment point of view or a planning point of view.

Mr. DOOLEY. Getting back to—and the EPA response on this is generally that they don't have the resources both in dollars and personnel to set up this separate branch? Is that what they're—

Mr. DAVIS. Well, we have just presented this proposal to the Agency several months ago, and we have not gotten a formal response. The IBA is going in to meet with the Agency to discuss implementing this, but we have not gotten a formal response yet.

Mr. CAULDER. In the past, the answer has been, "We don't have the resources to do it" because they're consumed with the reregistration process of chemicals.

Mr. WYLIE. The tiered approach of toxicology and environmental fate provides for tier 1 testing, which is quite simple for the biological products. When you move into tier 2 and tier 3, you get into very complex, long term, chronic testing where there are typically findings or responses in the testing, and there's a lot of technical analysis and input that has to be put into place. You can imagine someone having a biological registration package and a complex chemical one where the biological could be reviewed in a matter of weeks, sometimes even days, certain components, and may get tied up for 6 months or 9 months because the particular reviewer is involved in more complex issues.

Mr. DOOLEY. I'm unfamiliar with a lot of this. There was a lot of attention given to the subdivision M, which was supposedly to try to assist, enhance, and expedite registration of these products. There seems to be, though, agreement that this has not been effective. Why?

Mr. WYLIE. I think, from my point of view, it hasn't been effective because the leadership at EPA has not pushed the policy and not directed personnel to respond to that policy. Clearly, you need to set time lines, milestones, and enforce compliance to those, or things stretch out and delays and unpredictability occur.

Mr. DAVIS. If I could add one point, I think it's important to realize that subdivision M works in the sense that it reduces the data requirements, and that's what the guidelines were designed for. What we don't have is the urgency of getting that data reviewed.

Mr. DOOLEY. Say Mr. Stenholm and I were going to become strong advocates and go to the EPA and say that they need to set up this separate process and set up this separate branch, and EPA comes back to us and says, "Well, we don't have the financial resources nor the personnel that we can dedicate at this time because of their pressing demands on them elsewhere." Are there any alternatives out there which the industry could support in terms of helping to finance this separate branch and this process?

Mr. CAULDER. I think one of the concerns we would have—and basically what you're talking about are user fees—is that if you absolutely knew that the money would be used for what you were earmarking it for, you probably would get some support. I hate to sound like the skeptic, but when it comes in the big black box, what it gets used for out of our control would bother me. Intuitively, I have a problem with user fees because I think we as taxpayers pay the agencies to protect the public and us by registering these products, so it should just be part of our general operating budget.

But specifically I think you would find no real problem if we were assured that the end result would be what we thought we were paying for when we started it.

Mr. DOOLEY. If I can carry along that same line, for products of this nature, maybe a totally different alternative where if we could categorize these as being more environmentally friendly or not having the same toxic problems that some of our chemical tools have, is there any reason why we couldn't establish the adequate protocols for testing and take this outside of the EPA into a private sector review and analysis process that could give us the same level of assurance and protection that could assist the EPA in the registration, not totally, but in part?

Mr. CAULDER. I think, unfortunately, what has occurred in the EPA, as in some of our other agencies, is we have moved away from science-based decisions and factual things to subjective things about safety and all of those, and I think if you move away from the EPA this whole specter of, "Gee, who's doing the testing, and what's their credibility?" I think it would be very difficult to get anyone else to assume that, from a liability standpoint.

I think one of our basic problems and, to me, one of the basic questions facing us as a society is, how do we determine what is true? These processes have to be based on science, and we have moved away from that. We've moved into—the egalitarians just say, "Well, let's vote on what's true," and our regulatory procedures have to get back to being based on science.

Mr. DOOLEY. I appreciate your comments, and I share a lot of your frustrations there, too.

I'll turn it over to the chairman.

Mr. STENHOLM. Dr. Caulder, if we just got a wrench and got up under that hood, we could find out what's wrong with it, couldn't we?

Mr. CAULDER. It depends on how many people have their hand on the wrench. [Laughter.]

Mr. STENHOLM. Pursuing that line of thought a little further—and, Dr. Templeton, in your earlier comment, you made the statement that before you went further, you satisfied yourself as to the safety. Now, my assumption is all scientists satisfy yourselves as to the safety of that which you're working with. Either that, or you're grossly stupid. That's an assumption that I make. Then we get into the point that Dr. Caulder just made in responding to Mr. Dooley, and that is where we have now developed into a Nation in which we want to vote on it, and credibility of USDA, FDA, EPA, the Congress, any entity that we have under our constitutional law seemingly has difficulty with credibility. For us to pursue the purpose of which we're about, we need to satisfy the general public and, first, ourselves that we're developing a credible way of answering these very, very serious questions.

I guess the question I'm wanting to ask you now, within your own sphere of expertise and your own knowledge of science and other scientists, what degree—and I'll ask the question of you, Dr. Templeton. You satisfied yourself that it was safe. How many other scientists working in similar areas had some question as to the safety of the product that you referred to?

Mr. TEMPLETON. Well, to assure that it got reviewed, we published. We also issued a lot of publicity about the project as it developed. In fact, one of the highlight films during half-time of a nationally televised football game with the University of Texas, our university featured our project. It emphasized the use of naturally occurring things to control pests. We got a lot of publicity from this exposure and it was all favorable.

The key points are, first, I satisfied myself that our organism is specific, that it is genetically stable, that we were only augmenting the organism and it would fall back to background population levels after treatment. Then I contacted three eminent plant pathologists with experience in related diseases. I went to them personally and said, "This is what I have. What do you think? Do you think I ought to go with it or not?" and they agreed that "You're safe if you have demonstrated these things—that it is specific, that it's genetically stable, that it will perish if it doesn't have its own host to increase on."

Mr. STENHOLM. Now, at any stage of this—the publicity, the going to your peers—at what stage did any other scientist raise a question as to whether or not the product you're talking about was or was not safe, or did they?

Mr. TEMPLETON. No one did.

Mr. STENHOLM. Has anyone ever raised a question about the safety of the product that you're talking about in a scientific way?

Mr. TEMPLETON. Yes. A Canadian scientist has indicated that it might increase on dead soybean residue and, therefore, become a risk.

Mr. STENHOLM. When was this question raised?

Mr. TEMPLETON. This was raised several years after it was registered.

Mr. STENHOLM. What was the result of the questioning of that scientist regarding the safety of this product?

Mr. TEMPLETON. Well, it perhaps will have some bearing on its reregistration. It certainly had a bearing on the registration in Canada of a similar product, and they had to illustrate with experimentation that it was not a valid concern in that product.

Mr. STENHOLM. What was the nature of the safety question raised by the Canadian scientist?

Mr. TEMPLETON. That there might be a build-up of this organism on the residue of the crop if it was treated first with paraquat. In other words, if we killed soybeans with paraquat to harvest them sooner or to avoid deterioration and in a wet year, that the organism might build up on the crop and produce a lot of inoculum that could then affect some other plant. But we have a host specificity test, volumes of host specificity tests. We also know that it doesn't compete well with the naturally occurring microflora of crop residue, and then the Canadians applicants showed that their fungus disappeared quickly and did not reside in fields of wheat and lentils either.

Mr. STENHOLM. So they have researched it in Canada and have disproved the concern of that one scientist who raised the question?

Mr. TEMPLETON. They have satisfied the regulatory people in Canada, and Canada probably has a more stringent regulatory requirement on biological herbicides than we do. But that is unusual.

The Japanese Government, the Netherlands, the Germans, the English all have a cooperative arrangement or a cooperative climate to encourage development of these biologicals rather than an adversarial one.

In America we seem to think that we've got to have an adversarial-type of relationship between a regulatory agency and an applicant. If we continue that, we'll never be able to fully use biologicals. They are more like a grain varieties or like variety development. You have variety development all over our country for specific locations that are for the best crops in each location. In other words, biologicals are site-specific in addition to being host-specific.

Mr. STENHOLM. The statement was made a moment ago that it wasn't the money that concerns you as much as it's the time and the unpredictability, which, to me, time and unpredictability equal money. I mean, that's what it's all about. Most of these efforts are being developed in the private sector, and, therefore, investors, whether it be public or whether it be private—public in the sense of outside investors or your own money—time and unpredictability. That's what this whole question of minor use is all about. It's also what the question of alternative products is all about.

Where I was coming at in this question is, we're grasping looking for a way to satisfy—and I don't want to use 50 percent plus 1. I mean, I think this needs to be a much higher degree of satisfaction within the scientific community as to what's safe and what's not safe, and I don't want to pick a number, but 70/30 is better than 51/49 as far as satisfying the general public as to the relative safety, and 90/10 would be much better.

But to me, having looked at this issue now for years, this gets down, again, to another fundamental question that we have to resolve, and that is, what mechanism do we set up that establishes consensus and credibility. Each of you in your own private endeavors, you satisfy yourself, but you all suggest peer review. I have yet to meet the first scientist that's ever testified before this committee or the Veterans' Committee or any other committee that I've been involved in that says that they do not wish to have peer review, because certainly all of us in the public sector know that that's absolutely critical.

What kind of mechanism do we need to pursue on which all parties will agree, that once it has been peer reviewed and once it has been established that it is "safe," as best we can determine with current science.

Now, I believe—and this is a personal belief—that the overwhelming majority of all of the parties interested in this question agree to that process. Now, there are some that will never agree to that, and the ones that will never agree to the utilization of any kind of manmade insecticide, pesticide, et cetera, those need to be isolated for what they are, and it's a very small minority viewpoint, but they certainly are welcome and will always have their freedom to express themselves. But if we're going to establish credibility, it seems to me this is one area that we really need to delve into.

I don't have the answers today, but we're looking for them, because unless we achieve that goal, it's going to be very difficult for us to have the time and the predictability that's going to be re-

quired to develop alternative sources. It's also been very obvious to me that the questioning of pesticides, the same is true for biologicals. The moment that you start to suggest—and that's why I was interested in the pursuit of your product, and if there's anyone that ever questioned that, and then what happened when it was questioned, because I think it's very true on biologicals also.

Mr. WYLIE, I want to ask you a question. Why do you suggest taking biologicals out of the reduced-risk category of EPA? Aren't there both chemical- and nonchemical-based pesticides which can be considered reduced risk?

Mr. WYLIE. Absolutely. The reason that I propose that it be separated is that we already have in place the policy within the Agency to evaluate and register microbial biopesticides. They're trying to create a new policy which is going to get into a comparison of safety factors, and it's going to, basically, from my point of view, personal viewpoint—I'm not representing an association here at the moment—pit one product against another.

Just to create a hypothesis for you, you could have one product that had very low mammalian toxicity, had no impact on the environment, it didn't persist in the soil, but maybe it caused allergies in somebody, which is not unusual in a hypersensitive individual. In the other case, you might have a pesticide that did have a long residual in the soil and persisted, but didn't have an allergy impact on people. Now, who's going to make a decision there as to which product has the greatest benefit and greatest risk?

You take a microbial agent—if I can just digress for one moment, this will help you understand my answer. We just were successful after 22 months registering our company's first product. It's for control of cockroaches, and the cockroach is not a very esoteric market, but worldwide it's almost \$600 million at the manufacturers' level in terms of a market. This product is based on a naturally occurring fungus that was isolated from the soil. We could go right outside here on the lawn, or we could go to Japan, or we could go to China, down into Brazil, and we could find this fungus *metarhizium anisopliae*. It was discovered in 1880, has been used in field agriculture in China and Brazil for years. It does not grow at mammalian body temperatures.

We ran every required test, both environmental and toxicology test, that we had worked on with the Agency as the criteria for registration under tier 1. There was not a single test finding. That means that the tests were completely clean, and yet it took 22 months to register that product. That is the kind of complex situation you get involved in.

Now, when you start talking about products—and they could be biologicals, by the way, that have some response, and you get them into a mixed bag of trying to assess risk/benefit across a broad base where you have a class of potential alternatives to chemical pesticides, which are safe, clearly safer, that get thrown into that pot where we can't get them registered today in less than almost 2 years or, as Mr. Caulder indicated in his case, well over 2½ years, and who's going to suffer? It's going to be the farmer, it's going to be the American public.

Fifteen million people today in the United States are reputed to have allergies that are caused by cockroaches. Most people don't

know that. Should we take 2 years to put a product into commerce that can alleviate and minimize the amount of chemical sprays going into a house or a restaurant or a food establishment? I don't think so, and that's the problem that I see and why I believe clearly we should separate and address the near-term alternatives that are being offered by our small element of this industry.

Mr. STENHOLM. Mr. Smith.

Mr. SMITH. Thank you, Mr. Chairman.

I've read all your statements, and I apologize for not being here when you testified. The question always comes up, who do you believe? The question to me is simply, is there an organization outside the EPA that is above and beyond prejudice, maybe in the private industry side, that can give us some updated information regarding safety of a product, especially biologicals, that would speed up this process?

Mr. WYLIE. Well, you can search the annals of university people all around the country—for that matter, all around the world. There are renowned authorities who can comment upon the safety and the nature of many of the products that we're talking about here today as a separate organization, the National Academy of Sciences and others, but there are many independent scientists who I'm sure would be happy to contribute and testify before this committee.

Mr. CAULDER. Let me address that in general. Science is an iterative process for finding out the truth, and one of the problems scientists have is that when you're backed into the corner of "Can you assure me that under no circumstances at any time will anything bad ever happen?," a good scientist is always going to tell you, "No, I can't do that." So what happens with the scientific process within our agencies is that we always go down to the lowest common denominator of if it's at all possible, we don't want it, which gets to this risk-free society, which we can't have, and that gets you the risk versus benefits.

What it gets down to is what's possible versus what's probable. Most of the things with biologicals, it's not very probable you're going to have any problem at all with them, but when we get pinned to the wall and say, "Is it possible that colletotrichum, used for a rice herbicide, could have this happen?," Dr. Templeton's going to say, "Well, yes," because he's a good scientist. We are hung with the scientific method, and what that does is, it being an iterative process, we have the tendency to change our mind as we get new data, and, of course, then we get accused of we can't make up our mind.

This probability versus possibility is something that we need to deal with because if we always reduce it to what's possible, then the process will go on forever. The illustration I use is it's possible for people from another planet to testify here today, but we didn't set an extra seat for them, because it's not very probable, and if we always say is it possible, good scientists are always going to tell you that.

The great thing about science, to me, is twofold. One is, no one has the final say. It just doesn't happen. It took a part-time patent guy from Switzerland to dethrone Isaac Newton. His name happened to be Einstein. He was a pretty good patent guy. But no one

ever has the final say about these things. The second is, scientists are the only group I know who spend their entire lives trying to prove their peers wrong through this peer process that we talk about, and they do it in a fairly civilized way.

But it gets down to risk versus benefit, how much risk are we willing to accept, and who do we believe about those risks, and it's always a sliding scale, and you can kind of start on that scale anywhere you want to. What we need is good leadership that's willing to stand up and say, "We can't live in a risk-free society. The best method we have for finding out the truth is science, and we're going to make decisions based on science, not process."

Mr. SMITH. Thank you. That's exactly why I'm delighted to have Congressman Stenholm step up to the plate and take that risk. Thank you. [Laughter.]

Mr. STENHOLM. Mr. Dooley.

Mr. DOOLEY. I would concur with you, Dr. Caulder, that we're being intellectually dishonest if we say that we can eliminate risk. I guess that gets back to the issue that I have been, and I think all of us here on the panel have been, asking everyone that's appeared before us. Is somebody else out there—I mean, does Japan have a better method of registering this type of products? Does France? Does anyone have a better program that's in place now?

Mr. CAULDER. Not that I know of, because they all are wrestling with this same problem of how do we get down to the risk, and what risk are we willing to accept, and how quickly do we want to get products into the marketplace. I don't want this to sound as pejoratively as it probably will, but there's not a lot of incentive for bureaucratic operations to approve things. There's a big incentive for not approving them, because nothing happens then.

Mr. WYLIE. I would say that Europe, before the consolidation there and how the harmonization of regulatory, did have leadership in some countries that were more willing to aggressively move things forward, but the United States today, in the whole area of biological pesticide development, has a good technology lead. It's strong, and all of us end up—we compete in a worldwide, global marketplace, and we do have a technology lead. But we can lose that as quickly as we gained it.

In this industry, Mycogen, which Dr. Caulder represents, started back in about 1984, one of the leaders in the industry. It's taken a long time to bring products to market. It's costly, and it does concern us, the cost, and time does concern us, but, importantly, if we're not regulated in an effective, predictable way, we will lose our leadership, because other countries are going to step forward and provide the environment for new technologies to develop faster than we can do them here.

Mr. DOOLEY. I thank you all once again.

Mr. STENHOLM. You know, one of the myths that we continue to deal with in the media is that because something is natural, that it's safer, that a natural environment provides a safer environment for a human. It's a myth, but yet it's believed that natural is better. One of the concerns on the biological versus the nonbiological is that this becomes an "us versus them" kind of a debate, because in that case I think everybody loses. You haven't made that argument today, but there are those who would choose to do so.

You know, the incentive to approve, you made a very good point there, and I think this is where the Congress needs to accept some of the blame instead of pointing to the bureaucracy, as we often do. I think we're the ones who really need to analyze ourselves as we write these laws, to make sure that we don't create the incentive not to approve anything because the risk is so great to meet the standard that we have tried to set in trying to satisfy the general public.

I know that has been a fact in the past, and you can only look at the volume of the farm bills that we pass, the words that are in there, and then the difficulty that you get into in legal interpretation of those words, because every word gets in there because somebody wanted it in there for some purpose, and that purpose is not always a helpful purpose.

Mr. Smith or Mr. Dooley, do you have any other questions?

Mr. DOOLEY. No.

Mr. SMITH. Just one, Mr. Chairman.

I think we're all stretching trying to find another measurement of a standard besides maximum tolerated dose in one case. Mr. Dooley's asking you about other countries, and the problem is that we do rely on science, and the scientists do not rely upon their own information, saying maximum tolerated dose is unreliable. Is there any way that you all see that we can move away from that standard to something that's acceptable, to something that holds benefits in equal amounts to risk? It seems to me like we're way on the side of risk and not on the side of benefits.

Mr. TEMPLETON. I think that a major problem is that all of our regulations have derived from the chemical paradigm. Everybody regulates biological pesticides as if they were a chemical. We've backed away from that some but we need to do more. I think we need a biological paradigm to separate chemicals from biologicals.

Mr. SMITH. Anyone else?

Mr. WYLIE. I would just add mode of action is quite different often with the biological, at least the ones that EcoScience is focused on. The product that I referred to for cockroach control is not a toxin. It's a mechanical effect. The fungus has an enzyme response, a recognition on the surface of the insect, and it sends out a hyphae that penetrates the cuticle or the skin of the insect and then feeds on the inside of the insect. Now, what you do to test that type of product is entirely different than a synthetically derived chemical, so maximum tolerated dose is really not an appropriate testing procedure for that kind of product. So you do have a dichotomy there that has to be dealt with.

Mr. CAULDER. I think the problem goes back to the adage that the dosage makes the poison, and once we get into that, then we have this idea that we have to be able to quantify everything, and that gets you into generating numbers, which many scientists will tell you our ability to generate data has outstripped our intellectual ability to deal with it, in my opinion, because then you just flood everything with—it trivializes the data that you're producing to the point that anyone can get anything out of it that they want to, and that's where we get into problems. Scientific data are neither good nor bad data, they're just data, and when you start generalizing

them and letting everybody interpret them that were not involved in the generation of them, you lose the nuances.

I guess what I'm saying is everything just can't be quantified, yet we demand that we quantify everything. We want to know whether we take two aspirins or three or what, and you can't always do that in science, because you don't have these nice little pockets that you can put things in.

Mr. SMITH. Thank you.

Mr. STENHOLM. I thank all of you for very excellent testimony. I appreciate the additional comments that you've made. We look forward to working with each of you in the days ahead as we try to find the elusive answer. Thank you very much.

This hearing is hereby adjourned.

[Whereupon, at 1:40 p.m., the subcommittee adjourned, to reconvene, subject to the call of the Chair.]

[Material submitted for inclusion in the record follows:]

TESTIMONY OF ARTHUR R. BROWN, JR.
SECRETARY OF AGRICULTURE
NEW JERSEY DEPARTMENT OF AGRICULTURE

BEFORE

THE SUB-COMMITTEE ON DEPARTMENT OPERATIONS AND NUTRITION
U.S. HOUSE OF REPRESENTATIVES

JUNE 10, 1993

MR. CHAIRMAN, MEMBERS OF THE SUBCOMMITTEE:

AS NEW JERSEY SECRETARY OF AGRICULTURE, I WANT TO THANK YOU FOR THE OPPORTUNITY TO TESTIFY ON BEHALF OF BOTH NASDA AND THE STATE OF NEW JERSEY.

NASDA, THE NATIONAL ASSOCIATION OF STATE DEPARTMENTS OF AGRICULTURE, IS A NON-PROFIT, NON-PARTISAN ORGANIZATION OF PUBLIC OFFICIALS COMPRISED OF THE 50 STATE DEPARTMENTS OF AGRICULTURE AND THOSE FROM PUERTO RICO, GUAM, AMERICAN SAMOA AND THE VIRGIN ISLANDS.

MANY STATE DEPARTMENTS OF AGRICULTURE REGULATE THE USE OF PESTICIDES.

BEYOND THAT, ALL AGRICULTURE DEPARTMENTS WILL BE DEALING WITH THE FAR-REACHING AND POTENTIALLY DEVASTATING EFFECTS OF PRODUCTS LOST BECAUSE OF THE ECONOMICS OF THE RE-REGISTRATION PROCESS.

THE ISSUE OF THE REGISTRATION AND RE-REGISTRATION OF PESTICIDES BY THE FEDERAL GOVERNMENT WHICH IS BEFORE YOUR SUBCOMMITTEE IS MUCH MORE COMPLEX THAN IT MAY APPEAR.

TO PROPERLY ADDRESS THE RE-REGISTRATION ISSUE, THE SUBCOMMITTEE SHOULD TAKE A DETAILED LOOK AT EVERY ASPECT OF THIS PROCESS.

THIS INCLUDES ITS IMPACT ON VARIOUS SECTIONS OF THE FEDERAL INSECTICIDE, FUNGICIDE AND RODENTICIDE ACT, KNOWN AS FIFRA, AND THE FEDERAL FOOD, DRUG AND COSMETIC ACT.

IN NOVEMBER 1992, THE UNITED STATES GENERAL ACCOUNTING OFFICE REPORTED ITS FINDINGS ON THE INFORMATION SYSTEMS IMPROVEMENTS ESSENTIAL FOR EPA'S RE-REGISTRATION EFFORTS.

THAT STUDY ONLY LOOKED AT THE ADMINISTRATIVE BURDEN OF THE PESTICIDE REGISTRATION PROGRAM ON THE EPA'S OFFICE OF PESTICIDE PROGRAMS.

AS THE REPORT STATES, THIS IS NO SMALL TASK. SINCE FIFRA WAS ENACTED IN 1967, OVER 50,000 PESTICIDE PRODUCTS HAVE BEEN REGISTERED.

IN THE 1970s, DUE TO PUBLIC HEALTH AND ENVIRONMENTAL CONCERNS, MOST OF THE EXISTING ENVIRONMENTAL LAWS WERE ENACTED.

FIFRA ITSELF WAS AMENDED IN 1972 TO REQUIRE EPA TO RE-EVALUATE REGISTERED PESTICIDES, TAKING INTO ACCOUNT LONG-TERM HEALTH AND ENVIRONMENTAL EFFECTS.

IN 1988, CONGRESS SET A 1997 DEADLINE FOR COMPLETION OF MOST PESTICIDE REGISTRATION DECISIONS BY EPA. AS YOU HEARD ON TUESDAY, SO FAR EPA HAD REACHED FINAL DECISIONS ON ONLY 20 OF MORE THAN 20,000 PRODUCTS SUBJECT TO RE-REGISTRATION.

WE NOW REALIZE THAT MANY OF THE HEALTH AND ENVIRONMENTAL CONCERNS ABOUT LONG-TERM EFFECTS WERE NOT WELL-FOUNDED.

THE RESULTING RE-REGISTRATION REQUIREMENTS ONLY MADE THE PROCESS MORE COMPLEX, IN SOME CASES PROHIBITIVELY EXPENSIVE AND PROBABLY IMPOSSIBLE TO ACCOMPLISH IN OUR LIFETIMES.

IN A PRESENTATION TO THE NATIONAL ASSOCIATION OF FARM BROADCASTERS IN KANSAS CITY, MISSOURI LAST NOVEMBER, EPA'S OFFICE OF PESTICIDE PROGRAMS STATED THAT THE 1988 RE-REGISTRATION REQUIREMENTS HAD RESULTED IN MANY VOLUNTARY CANCELLATIONS BY REGISTRANTS.

THESE CANCELLATIONS REDUCED THE NUMBER OF REGISTERED PRODUCTS FROM 47,000 TO ABOUT 20,000 AND CUT THE NUMBER OF ACTIVE INGREDIENTS FROM 1,153 TO 676.

IN PARTICULAR, THE HIGH COSTS INCURRED BY THE RE-REGISTRATION PROCESS HAVE JEOPARDIZED THE FUTURE OF LOW-VOLUME PESTICIDES AND MINOR USE REGISTRATIONS.

MINOR USE PESTICIDES ARE ENDANGERED FOR ECONOMIC, NOT SAFETY, REASONS. AGRICHEMICAL COMPANIES SIMPLY CANNOT AFFORD TO DEVELOP OR KEEP THEM ON THE MARKET.

MR. CHAIRMAN, I THINK IT IS APPROPRIATE TO PUT THE TERM "MINOR USE CROPS" IN ITS PROPER 'MAJOR' PERSPECTIVE. IN 1990 U.S. AGRICULTURAL CROP SALES WERE VALUED AT APPROXIMATELY \$70 BILLION.

ABOUT \$30 BILLION, ALMOST HALF THE TOTAL VALUE OF AGRICULTURAL CROPS, CAME FROM THE SALES OF CROPS LIKE VEGETABLES, FRUITS, NUTS, SEEDS AND ORNAMENTALS, ALL OF WHICH FALL UNDER WHAT I CONSIDER A MISNOMER -- "MINOR CROPS."

THE 1987 CENSUS OF AGRICULTURE DATA ON CROP SALES BY STATES CLEARLY SHOWED THAT IN MANY STATES THESE SO-CALLED MINOR CROPS ARE A SIGNIFICANT PERCENTAGE OF THE VALUE OF ALL CROPS.

IN MY OWN STATE OF NEW JERSEY, FOR EXAMPLE, THE DATA SHOWED THAT THE VALUE OF MINOR CROPS WAS ONE OF THE HIGHEST IN THE NATION.

FOR NEW JERSEY THE VALUE OF MINOR CROPS IN 1987 WAS \$316 MILLION WHICH EQUALS 85% OF THE VALUE FOR ALL CROPS. THE 1987 DATA ON MINOR CROPS INCLUDED VEGETABLES, SWEET CORN, MELONS, FRUITS, NUTS, BERRIES, NURSERY AND GREENHOUSE CROPS.

SINCE THEN, THE VALUE OF THESE CROPS HAS INCREASED AS THE ALTERNATIVE AGRICULTURE MOVEMENT SHIFTED GROWERS MORE TOWARDS THESE CROPS.

TO GIVE YOU AN EXAMPLE, RAISING SPECIALTY CROPS, SUCH AS CHINESE VEGETABLES, HAS BECOME A VIABLE INDUSTRY IN NEW JERSEY DUE TO AN EXPANDED ETHNIC MARKET.

ONCE THE 1987 DATA HAS BEEN UPDATED, I BELIEVE IT WILL SHOW THAT THE CURRENT VALUE OF MINOR CROPS IN NEW JERSEY IS WELL OVER THE 85% CALCULATED IN 1987.

PRODUCTION OF FRUITS, VEGETABLE AND OTHER SPECIALTY CROPS IS IN SERIOUS TROUBLE ACROSS OUR NATION. CONSUMER DEMAND IS STRONG BUT AMERICAN PRODUCERS COULD LOSE THIS MARKET OPPORTUNITY.

WE MUST CHANGE OUR POLICIES TO ASSURE CONTINUED PRODUCTION OF THESE SO-CALLED MINOR CROPS THROUGH THE AVAILABILITY OF SAFE, EFFECTIVE PESTICIDES OR OTHER ALTERNATIVES.

NOT ONLY IS THE AVAILABILITY OF CURRENTLY REGISTERED MINOR USE PESTICIDES THREATENED. THE PROSPECTS FOR NEW REPLACEMENT PRODUCTS AND NON-CHEMICAL ALTERNATIVES ARE FEW, IF ANY.

THE COSTS OF RESEARCH, DEVELOPMENT AND REGISTRATION EXCEED THE POTENTIAL DOLLAR VALUE OF THE MARKET.

MANY ECONOMISTS AND OTHER SCIENTISTS HAVE CLEARLY DEMONSTRATED THAT IT IS IMPOSSIBLE TO ACHIEVE A ZERO-RISK SOCIETY. AND WE ALL KNOW THAT WITHOUT PESTICIDES, EITHER NATURAL OR SYNTHETIC, PESTS WOULD DEVOUR CROPS, CAUSING WORLDWIDE FAMINE, A RESULT NONE OF US WANT.

PROFESSOR BRUCE AMES OF THE UNIVERSITY OF CALIFORNIA, A LEADING AUTHORITY ON CANCER AND CARCINOGENS, HAS STATED THAT EATING MORE FRUITS AND VEGETABLES IS THE BEST WAY -- BESIDES GIVING UP SMOKING -- TO LOWER THE RISK OF CANCER AND HEART DISEASE.

FRUITS AND VEGETABLES CONTAIN VITAMINS, ANTI-OXIDANTS AND FIBER, ALL OF WHICH ARE IMPORTANT WEAPONS IN THE WAR AGAINST CANCER.

RECENT SCIENTIFIC STUDIES HAVE CAUSED MORE AND MORE TOXICOLOGISTS TO QUESTION THE CURRENT CANCER TESTING PROTOCOLS USED FOR TESTING CHEMICALS IN ANIMAL STUDIES.

THERE IS INCREASING SCIENTIFIC EVIDENCE THAT IT MAY BE THE HIGH DOSE, RATHER THAN THE CHEMICAL ITSELF, WHICH IS THE RISK FACTOR FOR CANCER.

AT A VERY LOW LEVEL OF CHEMICAL EXPOSURE, SUCH AS THAT EXPERIENCED BY HUMANS THROUGH PESTICIDE RESIDUES, THE INCREASED CELL DIVISIONS WHICH LEAD TO CANCER IN STUDY ANIMALS DO NOT OCCUR.

IT IS INTERESTING TO NOTE THAT DR. AMES' RESEARCH HAS SHOWN THAT 99.99 PERCENT OF ALL DIETARY PESTICIDES ARE NATURALLY PRODUCED BY PLANTS. MOST AMERICANS CONSUME ABOUT 1,500 MILLIGRAMS OF THESE NATURAL PESTICIDES EACH DAY.

IN CONTRAST, DATA FROM FDA'S RESIDUES STUDIES SHOW THAT MOST PEOPLE INGEST A DAILY AVERAGE OF ABOUT 0.09 MILLIGRAMS OF SYNTHETIC CHEMICALS, INCLUDING SYNTHETIC PESTICIDES.

BASED ON THIS EVIDENCE, I BELIEVE THAT THE AMOUNT OF INFORMATION REQUIRED FOR PESTICIDE REGISTRATION UNDER SECTION 6(A)(2) OF FIFRA IS TOO EXTENSIVE, UNJUSTIFIABLY COSTLY AND UNNECESSARY AND WILL CAUSE THE REGISTRATION PROCESS TO BE UNWORKABLE.

THE RECENT U.S. DISTRICT COURT DECISION IN LES V. REILLY UPHOLDING A STRICT READING OF THE DELANEY CLAUSE HAS ADDED TO THE INHERENT PROBLEMS OF THIS PROCESS.

EPA RELEASED A LIST OF OVER 30 PESTICIDES WHICH COULD POSSIBLY BE AFFECTED BY THE LES DECISION. EPA ADMINISTRATOR CAROL BROWNER HAS STATED PUBLICLY THAT EPA DOES NOT BELIEVE THAT THESE PESTICIDES POSE AN UNREASONABLE RISK TO PUBLIC HEALTH BASED ON AVAILABLE DATA.

MR. CHAIRMAN, I KNOW THAT OTHER BILLS HAVE BEEN PROPOSED IN THE CURRENT CONGRESS ON THAT ISSUE. WITH REGARD TO THESE BILLS, I WOULD LIKE TO STATE FOR THE RECORD THAT I SUPPORT HR 1627, THE LEHMAN-BLILEY-ROWLAND BILL (THE FOOD QUALITY PROTECTION ACT OF 1993).

THIS BILL SETS A UNIFORM NEGLIGIBLE OR DE MINIMIS RISK STANDARD FOR PESTICIDE RESIDUES IN FOOD AND ALLOWS EPA TO FOCUS ON THE HIGHEST RISK PESTICIDES.

I ALSO STRONGLY URGE THE COMMITTEE TO PASS HR 967, THE MINOR CROP PESTICIDES ACT OF 1993, WHICH AMENDS FIFRA. THERE ARE SEVERAL PROVISIONS IN THE AMENDMENTS WHICH WILL HELP THE AGRICULTURE INDUSTRY. FOR EXAMPLE:

- * REGISTRANTS WOULD BE PROVIDED AN ADDITIONAL 10 YEARS OF EXCLUSIVE USE DATA TO SUPPORT A MINOR USE.
- * THE EPA WOULD HAVE TO REVIEW AND DECIDE ON APPLICATIONS FOR MINOR USE PESTICIDES WITHIN 6 MONTHS OF SUBMISSION.
- * NECESSARY RESOURCES WOULD BE PROVIDED TO USDA TO ASSIST WITH MINOR CROP ISSUES.
- * RESOURCES WOULD BE PROVIDED TO BOTH EPA AND USDA TO ASSIST IN REGISTERING AND RE-REGISTERING MINOR USE CHEMICALS.

AS I HAVE STRESSED THROUGHOUT MY TESTIMONY, THIS IS NOT JUST A FARMER ISSUE. SIGNIFICANT FINANCIAL IMPACTS WOULD ALSO BE FELT BY PROCESSORS AND CONSUMERS IF SOME MINOR USE PESTICIDES WERE NO LONGER AVAILABLE.

ULTIMATELY, THE CONSUMER COULD SEE LESS VARIETY OF FRESH FRUITS AND VEGETABLES, LOWER QUALITY AND HIGHER PRICES IN THE MARKETPLACE.

OF COURSE, ECONOMIC CONSIDERATIONS SHOULD NOT BE ALLOWED TO OUTWEIGH THE PARAMOUNT CONCERNS OF MAINTAINING STRONG SAFEGUARDS FOR PUBLIC HEALTH AND THE SAFETY OF THE FOOD SUPPLY.

I BELIEVE THAT HR 967 MAINTAINS THESE ESSENTIAL PROTECTIONS WHILE PROVIDING SIGNIFICANT BENEFITS TO BOTH AGRICULTURE AND CONSUMERS.

ALTHOUGH THERE IS PROVISION EMERGENCY EXEMPTIONS UNDER WHICH CERTAIN MINOR USE PRODUCTS COULD STILL BE APPLIED, AS A PRACTICAL MATTER SUCH EXEMPTIONS ARE USUALLY VERY DIFFICULT AND TIME-CONSUMING TO GET.

DETAILED IMPACT DATA, SUCH AS CROP LOSS ESTIMATES DUE TO THE TARGET PEST, ARE REQUIRED IN THIS PROCESS.

IF THIS DATA IS NOT IMMEDIATELY AVAILABLE OR SIGNIFICANT, AS IN THE CASE OF MINOR USE CROPS OR PESTS, FOR EXAMPLE, MITES IN HONEYBEES, THEN IT IS ALMOST IMPOSSIBLE TO OBTAIN EMERGENCY REGISTRATION.

THE EMERGENCY EXEMPTION PROCESS COULD ALSO BE STREAMLINED FOR PLANT OR ANIMAL PEST REGULATORY PROGRAMS.

IN NEW JERSEY PESTICIDE APPLICATIONS ARE REGULATED BY THE NEW JERSEY DEPARTMENT OF ENVIRONMENTAL PROTECTION & ENERGY. THAT AGENCY AGREES WITH MY REQUEST THAT YOUR COMMITTEE TAKE THE FOLLOWING ACTIONS:

1. ESTABLISH A CLEARINGHOUSE WHICH WOULD SERVE AS A ONE-STOP CENTER FOR REGISTRANTS TO GET ANSWERS ON QUESTIONS CONCERNING REGISTRATION AND RE-REGISTRATION.
2. ENHANCE THE EXISTING 1R-4 PROGRAM WHICH HAS GENERATED USEFUL DATA FOR REGISTERING PESTICIDES USED FOR MINOR CROPS, AS SHOWN IN TESTIMONY FROM DICK GUEST OF RUTGERS UNIVERSITY.
3. SUPPORT THE INTEGRATED PEST MANAGEMENT PROGRAM BASED AT THE RUTGERS COOPERATIVE EXTENSION SERVICE IN NEW JERSEY AND STRONGLY SUPPORTED IN NEW JERSEY.

BASED ON DATA FROM THIS PROGRAM, RECOMMENDATIONS ARE MADE SO THAT PESTS ARE PROPERLY MANAGED AND PESTICIDE APPLICATIONS ARE REDUCED.

CANCELLATION OF THE PESTICIDES ON THE EPA LIST WILL HURT THIS PROGRAM AND IMPACT ITS GOAL OF CAREFUL PESTICIDE USE.

4. PROVIDE AN EXPEDITED PROCESS FOR REGISTRATION OF PESTICIDE PRODUCTS THAT ARE CONSIDERED LOW-RISK, SUCH AS BIOLOGICALS, WHICH MAY PROVIDE ALTERNATIVE TOOLS NEEDED FOR MINOR CROP PRODUCTION.

ONCE AGAIN I REMIND YOU NOT TO BE MISLED BY THE TERM "MINOR USE" AS IT APPLIES TO EITHER PESTICIDES OR THE CROPS THEY PROTECT. THESE CROPS ACCOUNT FOR NEARLY HALF THE TOTAL AGRICULTURAL VALUE OF OUR NATION'S CROP SALES.

MOREOVER, MANY OF THESE ARE THE VERY CROPS THAT MEDICAL AND SCIENTIFIC RESEARCHERS ARE ENCOURAGING US TO EAT TO IMPROVE OUR HEALTH AND LONGEVITY.

IT WOULD BE A CRUEL TWIST OF FATE IF BUREAUCRATIC REQUIREMENTS WITH LITTLE BASIS IN SCIENCE OR FACT WERE ALLOWED TO JEOPARDIZE OUR ACCESS TO THESE VITAL PRODUCTS.

COPIES OF MY TESTIMONY HAVE BEEN PROVIDED TO ALL MEMBERS AND I WILL BE HAPPY TO ANSWER QUESTIONS FROM THE SUB-COMMITTEE.

TESTIMONY SUBMITTED

BY

RICHARD T. GUEST, PH.D.
OFFICE OF IR-4COOK COLLEGE/NEW JERSEY AGRICULTURAL EXPERIMENT STATION
RUTGERS UNIVERSITY

Mr. Chairman and members of the subcommittee, thank you for the opportunity to speak on behalf of the IR-4 Project regarding the operation and effectiveness of the program in registering pesticides for minor crops. My name is Richard Guest and I have been associated with the program for 20 years. I presently serve as National Director.

I would like to preface my testimony by mentioning that I have just returned from an International Symposium on Minor Uses in Braunschweig, Germany where I was a guest of the German government. I was invited to this symposium to present a paper on the organization, operation and accomplishments of the IR-4 Project. Common market nations are now recognizing the seriousness of the minor use problems and are seeking ways to find a solution. They have heard of the U.S. minor use program and are anxious to learn more about it. Dr. Frederick Klingauf, President of the Federal Biological Research Centre for Agriculture and Forestry, who chaired the symposium, stated in his concluding remarks that IR-4 is an effective program and could well serve as an excellent model for European Community nations to pattern after in search for a solution to their minor use problems.

BACKGROUND.

Producers of agricultural commodities typically depend on the agricultural chemical industry to provide them with safe and effective chemical pesticides to supplement their pest management practices. As the costs for meeting regulatory requirements increase, pesticide registrants tend to concentrate their registration efforts in areas where economic returns justify research and development costs. This has resulted in a greater number of registrations for the large acreage crops such as corn (72.3 million acres), cotton (11.5 million acres), soybeans (60.7 million acres) and wheat (76.6 million acres). However, producers of fruits, nuts, vegetables and specialty crops such as hops, mint and ornamental plants have a limited number of pest control products available to them compared to major crop producers. While the total acreage of minor crops is less than 8 million acres, the combined value of these crops is greater than \$24 billion annually or about 40% of all agricultural crop sales. One-half of all states have minor crop sales equal to or exceeding 50% of their total annual crop sales. For many states such as California, Florida, Georgia, Hawaii, New Jersey, North Carolina, Oregon, Pennsylvania and Washington, minor crops make up a very sizable portion of all crop sales.

It is generally agreed that a minor use is any use of a pest control product for which the sales volume is insufficient to justify the cost by a commercial registrant to obtain a registration. This may relate to the general or frequent use of a product on a low volume crop or it may apply to the infrequent or localized use of a product in a high volume crop. In either case, the problem of obtaining clearances for the minor crop/minor use markets is primarily one of economics. The difficulty in registering new pesticides, and the loss of existing registrations due to reregistration, is a serious threat to continued production of abundant, high quality commodities.

ORGANIZATION AND STRUCTURE.

In 1963, Directors of State Agricultural Experiment Stations recognized the minor use problem and, working with the U.S. Department of Agriculture - Cooperative States Research Service (CSRS), initiated Interregional Research Project No. 4 (IR-4). From this beginning, a cooperative effort has developed which now involves the U.S. Department of Agriculture (USDA), the U.S. Environmental Protection Agency (EPA), State Agricultural Experiment Stations (SAES), the Cooperative Extension Service (CES), agricultural chemical companies, commodity organizations and individual growers.

The IR-4 minor use program has grown in scope since its beginning. In 1975, Regional Leader Laboratories were established at SAES to provide regional coordination and analytical services. In 1976, the USDA-Agricultural Research Service (ARS) established a minor use program to provide further support for IR-4. The objectives of IR-4 were expanded in 1977 to include registration of pesticides needed for the protection of nursery and floral crops, forestry seedlings and turfgrass. The program was further expanded in 1982 to include the registration of biological pest control agents such as microbials and biochemicals. An IR-4 Headquarters staff provides the leadership and overall coordination for the diverse components of this national program.

The objectives of the IR-4 minor use program are:

- to obtain minor use and specialty use pesticide clearances and assist in the maintenance of current registrations, and
- to further the development and registration of microbial and specific biochemical materials for use in pest management systems.

In order to accomplish these objectives, an organization has been developed which involves the coordinated effort of both state and federal components (Figure 1). The program includes a National Headquarters, located at the New Jersey Agricultural Experiment Station (NJAES) and a management team consisting of administrators and technical representatives from state land grant universities and USDA; and a National Director who is employed to coordinate the overall minor use program. IR-4 also consists of four Regional Leader Laboratories, each with a director who serves as a member of the Technical Committee, and Regional Coordinators for field and laboratory studies. Regional laboratories are located at state land grant universities in Michigan, California, Florida and New York. Satellite laboratories at other land grant universities assist in the analysis of residue samples. Personnel at the regional leader laboratories interact with state liaison representatives at each state land grant university and with IR-4 Headquarters personnel.

A companion minor use program is administered by USDA-ARS. This program is headquartered at the Agricultural Research Center in Beltsville, MD and interfaces with three ARS liaison representatives in each of the four agricultural regions and with three ARS analytical laboratories. The ARS minor use program operates in concert with the IR-4 Project in the clearance of minor uses.

Fewer than 30 professional full-time equivalents are supported by IR-4 funding.

OPERATION.

IR-4 is a service-oriented research program. The scope of IR-4 is limited to developing efficacy, crop safety and magnitude of the residue data which are incorporated by Headquarters scientists into a tolerance petition and submitted to EPA for approval. Once a tolerance or exemption from the requirement of a tolerance is established, it is the responsibility of a commercial registrant to request EPA approval of a label for the use.

IR-4 is a grass roots organization with pest control requests initiated by farmers, nurserymen, commodity organizations, agricultural scientists and extension personnel. Figure 2 shows the flow of a request from initiation to research planning together with the operational responsibilities and decision criteria used in evaluating requests and establishing priorities. From the beginning, each request is subjected to a rigorous review process intended to assure equitable and efficient handling of all clearance needs and equal consideration for all segments of agriculture.

Minor use pest control requests are directed through state and federal liaison representatives to regional pesticide coordinators for initial review and then to IR-4 Headquarters for further review. Screening by Headquarters personnel includes concurrence by the agrichemical registrant and review by EPA for registration data gaps. Clearance requests with no serious registration impediments are included in a list of candidate projects for review at annual regional IR-4 liaison meetings and national workshops. These committees establish priorities for local (state/regional) and national needs based on criteria such as availability of alternatives, importance of the pest problem, lack of data gaps and value in IPM programs. Following prioritization, a tentative research program is developed by regional coordinators, regional analytical chemists and Headquarters coordinators where completion of existing projects, resource capabilities and economic impact are considered along with priority ratings. Cooperators to carry out field research are sought among the state and federal agricultural research community as well as among private consultants. Cooperating scientists typically receive \$2000 to \$3000 per trial. IR-4 analytical laboratories generally carry out the magnitude of the residue studies required by EPA with occasional assistance from corporate or commercial analytical establishments.

All research sponsored by IR-4 is conducted according to EPA Good Laboratory Practice Standards (GLPS). These Standards require Standard Operating Procedures for both field and laboratory research phases and provide for documentation of testing

procedures. Central to EPA GLPS are field and laboratory protocols which detail each phase of the research program. IR-4 fully supports GLP procedures and has sponsored two workshops to train IR-4 cooperators. In addition, IR-4 employs Quality Assurance Officers who assure that field and laboratory testing meet the GLPS. It is conservatively estimated that GLP procedures add one-third to the cost of the program.

The final step in the clearance process is reviewing and assembling all data relevant to a given project into a petition that requests the establishment of a tolerance or exemption from the need of a tolerance on a food commodity. This clearance document is submitted first to the prospective registrant for concurrence and then to EPA for review and approval. When a tolerance or exemption is established, it is the responsibility of the commercial registrant to properly label the use and make the product commercially available to the agricultural industry.

An important element in the operation of the IR-4 minor use program is the IR-4 Commodity Liaison Committee. This committee was established in 1991 and consists of 22 members who are either farmers or representatives of commodity organizations. The purpose of the IR-4 Commodity Liaison Committee is to provide guidance and advice on the effectiveness of the program in serving the needs of the producers of minor crops and in protecting the health and safety of the public.

ORNAMENTALS PROGRAM.

In 1977, the IR-4 Project was expanded to assist in the registration of pesticides on commercially grown ornamentals, including floral and foliage plants, woody nursery stock (both container and field grown), Christmas trees, turf and forest uses. The wholesale value of the ornamentals industry in the U.S. is estimated to be in excess of \$7 billion per year.

The operation of the IR-4 Ornamentals Program is handled in a similar manner to the food use program. Needs are expressed to IR-4 from nurserymen, state and federal research scientists and extension personnel; registrants are contacted for their concurrence; and prioritized lists of research projects are developed with input from regional committees and national workshops. Priorities are established similarly to food use projects with the importance of pest problems, availability of alternatives and potential value in IPM programs being major considerations. IR-4 Regional Coordinators contract with state and federal research scientists to carry out efficacy and phytotoxicity testing. Since no residue data are required and no tolerances are involved, registration of pesticide uses on ornamental commodities is less complex, less time consuming and less expensive than food use clearances. Data developed from the IR-4 research program are forwarded to registrants with the request that the use be included in product labelling.

BIORATIONALS PROGRAM

In 1982, IR-4 added the development and registration of biorational materials as an objective to the Project Statement. "Biorational" is a coined term which includes microbial pest control agents (e.g. bacteria, fungi, viruses and protozoans) and biochemical control agents (e.g. insect pheromones, attractants, insect growth regulators and plant growth regulators) all of which require data to support an EPA tolerance or exemption. They generally have a unique mode of action and are considered "safer" than conventional pesticides. Because of their high specificity, biorationals have limited market potential. Thus, there are weak economic incentives for commercial development of these products.

Requests for biorational clearances originate with state or federal research scientists in the form of proposals to support research on specific uses. All biorational proposals are reviewed against IR-4 Biorational Research Program Guidelines and require approval by the IR-4 Technical Committee before funds are committed. In the microbial and biochemical area, IR-4 funds small and large scale field efficacy trials and may assist in the development of EPA required safety and toxicology data. When the necessary data are obtained, IR-4 submits a petition to the registrant and then to EPA to support the tolerance or exemption and the registration.

Research on biorational pest control products is typically expensive and time consuming. For example, IR-4 recently submitted a petition to EPA for an exemption for the Codling Moth Granulosis Virus (CMGV) for use on apples, pears, walnuts and plums. It required ten years to develop the data to support this petition and cost in excess of \$1 million, with funds contributed by IR-4, the state of California, environmental groups and individual growers.

In order to provide greater support for the registration of biorationals, the IR-4 Technical Committee has voted to earmark 15% of all funding above the FY 93 base \$3.5 million budget to biorationals. IR-4 also seeks to establish coalitions with other organizations with similar interests in biologicals in order to leverage resources.

STRATEGIC PLAN

Historically, IR-4 has focused on the registration of new pesticides for minor uses. However, the 1988 amendments to the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA 88) have had a significant impact on minor use registrations. FIFRA 88 requires that all pesticides and uses registered prior to November 1984 be reregistered on an accelerated nine year timetable against current registration standards.

Exactly the same economic considerations that impede the registration of new uses for minor crops affect the reregistration of existing uses for minor crops. For this reason, IR-4 has been called upon to support needed minor use reregistrations

in instances where current registrants find it economically impractical to do so. Early surveys of agricultural producers conducted in cooperation with state agricultural experiment stations, contacts with commercial pesticide registrants, and workshops to evaluate the need for existing registrations on minor crops all strongly suggested that the effect of minor use reregistration, combined with an increasing backlog of new minor use registrations, would at least quadruple the workload of IR-4. This realization caused IR-4 to evaluate its resources and to develop a Strategic Plan to increase the number of annual project completions to about 500 per year. The IR-4 Strategic Plan called for substantial increases of both field and analytical capabilities including the establishment of field research centers and additional analytical laboratories at SAES; additional funding for ornamental registrations; and an increased commitment to biorational registrations. The cost of the plan was initially put at \$12M annually based on a 1990 start-up date. This figure was subsequently revised to \$14M per year.

The management and structure of the IR-4 Project and the adequacy of the Strategic Plan were carefully reviewed in late 1990 by a CSRS Peer Review Team and in 1991 by a GAO program audit. Aside from compliments on the past achievements of the program and for the Strategic Plan for addressing future clearance needs, both reports cited budgetary constraints as the principal reason the program had not achieved its full potential. In fact, the first conclusion of the GAO Report was that IR-4 would not complete research to support priority registration and reregistration of pesticide needs by the 1997 deadline. Funding was given as the reason.

FUNDING.

Total funding available from USDA for FY 93 is \$6.1 million. USDA-CSRS has requested an increase of \$6.5 million in the FY 94 budget for IR-4 which would result in total funding of \$12.6 million. This dollar amount approaches the \$14 million funding level recommended in the IR-4 Strategic Plan for meeting the Projects registration and reregistration objectives.

Federal funds available to the program are highly leveraged by research institutions through direct and indirect resources such as technical and administrative assistance, laboratories, land and equipment. It is estimated that for each federal dollar directed in support of the program, three dollars are contributed by host research institutions.

In addition to USDA monies appropriated for project support, EPA annually provides a grant to IR-4 to fund the National IR-4 Workshop for establishing priorities. The Agency also supports a full-time EPA chemist located at IR-4 Headquarters and a minor use officer located at the Agency's Washington Headquarters. In addition, EPA waives all fees for tolerance petitions submitted by IR-4 since they are deemed to be in the public interest.

Growers and grower organizations annually contribute substantially to the program either through direct funding of specific projects or through assistance in field and laboratory testing. In 1992, the commodity industry contributed about \$500,000 to IR-4 to support minor use clearance projects. Similarly, the agricultural chemicals industry provides financial aid to the program by direct contributions, sample analysis in their laboratories and by providing test substances to cooperators.

ACCOMPLISHMENTS.

IR-4 receives about 200 food use clearance requests each year and currently has a backlog of more than 1400 candidate research projects. From the beginning of the program in 1963 through calendar year 1992, IR-4 has been responsible for 4157 minor food use clearances, or about 138 clearances per year. However, clearances have been declining because of funding constraints, additional data requirements and the requirements mandated by GLPS. In 1991 and 1992, IR-4 was responsible for 122 and 120 minor food use clearances respectively.

The IR-4 Ornamentals Program receives about 250 clearance requests each year and has a backlog of about 800 candidate projects. During the 16 year history of the Ornamentals Registration Program, IR-4 has produced data to support over 3600 pesticide registrations on ornamental crops.

Since initiation of the IR-4 Biorationals Registration Program in 1982, IR-4 has received 46 biorational clearance requests, has funded 15 research proposals and has contributed to the clearance or label expansion of eight of the biorationals currently registered by EPA. IR-4 recently submitted petitions to EPA requesting exemptions from the requirement of a tolerance for Pseudomonas fluorescens for the control of bacterial blotch on cultivated mushrooms and for the Codling Moth Granulosis Virus (CMGV) for control of codling moth larvae on apples, pears, walnuts and plums.

CONCLUSION.

Since its inception, IR-4 has been responsible for one-half of all pesticide registrations on minor food crops and 80% of all pesticide registrations on ornamentals. The success of IR-4 is attributable mainly to the cooperative nature of the program which brings together federal and state agencies, commodity producers, agricultural chemical registrants, state and federal agricultural scientists and chemists and a team of IR-4 coordinators all working toward a common purpose. IR-4 benefits both producers and consumers of minor crops by assuring an adequate supply of safe, effective and properly labelled crop protection products.

Figure 1

SECRETARY OF AGRICULTURE

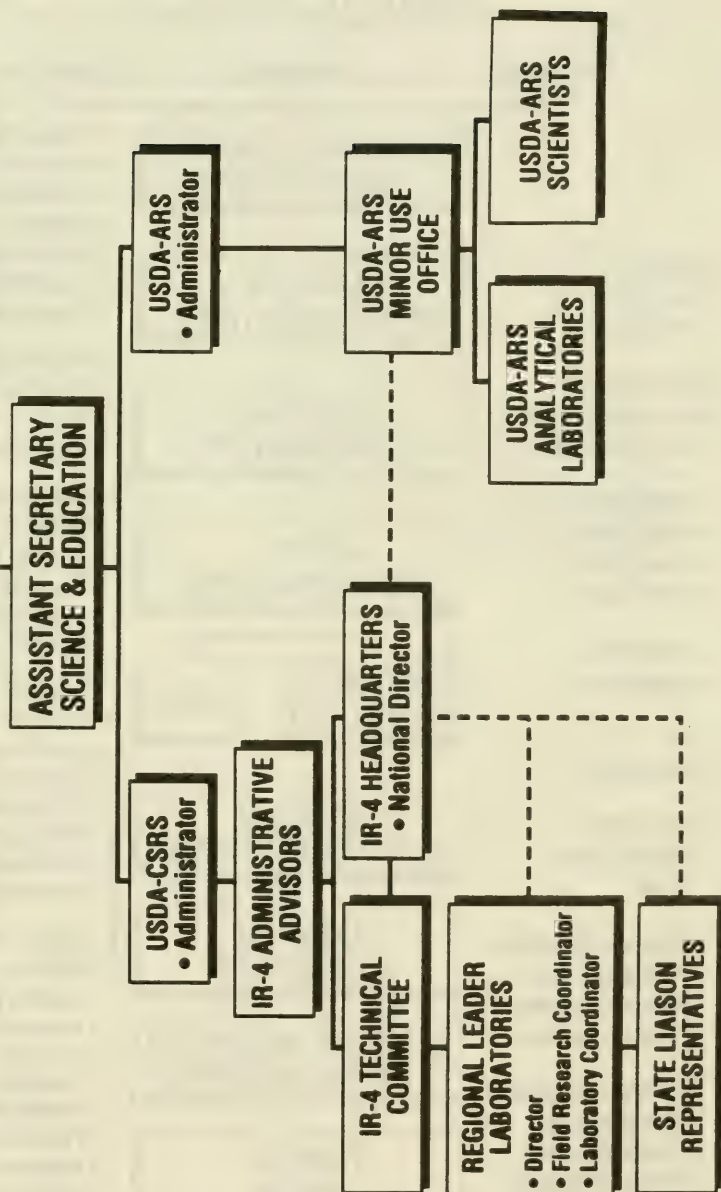
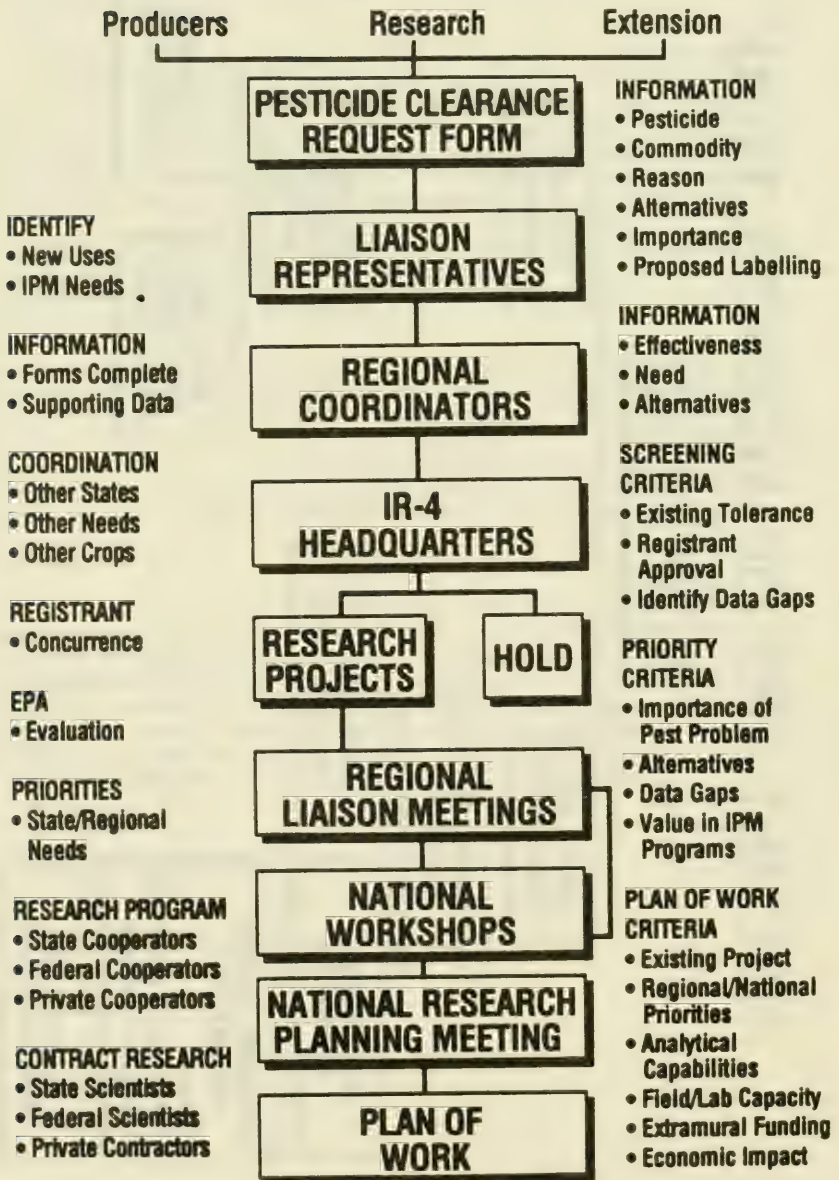


Figure 2

CLEARANCE REQUESTS



BEFORE THE SUBCOMMITTEE ON
DEPARTMENT OPERATIONS AND NUTRITION OF THE
HOUSE COMMITTEE ON AGRICULTURE

HEARINGS ON REGISTRATION AND REREGISTRATION ISSUES

STATEMENT OF THE MINOR CROP FARMER ALLIANCE

Mark Maslyn, Vice Chairman
Minor Crop Farmer Alliance And
Director of Governmental Affairs
American Farm Bureau Federation
600 Maryland Avenue, SW
Washington, D.C. 20024
(202) 484-3600

Daniel A. Botts, Chairman
Technical Committee of the
Minor Crop Farmer Alliance And
Director, Environmental and Pest
Management Division of the
Florida Fruit & Vegetable Assn.
Post Office Box 140155
Orlando, Florida 32814-0155
(407) 894-1351

Counsel:

Edward M. Ruckert
Jerry C. Hill
McDermott, Will & Emery
1850 K Street, NW, Suite 450
Washington, D. C. 10006
(202) 778-8214

Submitted: June 10, 1993

BEFORE THE SUBCOMMITTEE ON
DEPARTMENT OPERATIONS AND NUTRITION OF THE
HOUSE COMMITTEE ON AGRICULTURE

HEARINGS ON REGISTRATION AND REREGISTRATION ISSUES

STATEMENT OF THE MINOR CROP FARMER ALLIANCE

Farmers throughout the U.S. are feeling the effects of a growing problem. Many safe pesticide uses are being dropped voluntarily by pesticide manufacturers because one, the costs or time constraints of developing data required by the Environmental Protection Agency's (EPA) reregistration program exceed the expected return from the sale of such pesticides and two, because the companies do not have the time or resources under the current regulatory procedures to generate the necessary data. The issue is one of economics or time constraints, rather than health and safety concerns. We believe that the number of uses being dropped for this reason is increasing at an alarming rate. The Minor Crop Farmer Alliance (the Alliance) has provided the Committee members a state by state survey to better identify the extent of the problem.

In addition, we believe that replacement crop protection tools -- chemical or non-chemical -- are not being developed at a rate fast enough to address the needs of farmers. The funding and organizational focus of agricultural research, integrated pest management, IR-4 and other similar programs, is not keeping pace with the needs of farmers.

In June 1991, representatives of several farmer organizations met in Dallas, Texas to assess whether the losses of minor crop protection tools were negatively impacting production agriculture. It was determined that this was indeed a growing national problem.

THE MINOR USE PROBLEM

The early roots of this problem can be traced back to 1972 with the revision of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). Essentially, the regulatory focus went from assuring the efficacy of pesticides, to requiring

manufacturers to provide sufficient data demonstrating that use of a pesticide in accordance with label directions would not present an unreasonable adverse effect to the environment. The Alliance supports this change in focus as long as sound science is the basis for decisions.

In amending FIFRA, Congress had a problem to address, namely what approach should be taken with older pesticides previously registered by the United States Department of Agriculture (USDA). There seemed to be two approaches to consider.

The first was to cancel all the pesticide registrations for which adequate data did not exist and then restore them after sufficient data had been developed. The impact of this approach on both the agricultural community and the food supply became readily apparent, and it was not seen as a workable solution.

The second approach was to essentially "grandfather" in the USDA registered products and require manufacturers to update their data packages within a short period of time (i.e. five years). This seemed to be simple and reasonable enough, so it was the approach selected.

Unfortunately, time eclipsed intentions, and by 1978 it became clear that reregistering existing chemicals would take much longer than Congress or EPA ever imagined.

Almost 16 years went by. By 1988, most chemicals had not yet completed reregistration. In fact, of the 600 active ingredients contained in the more than 50,000 pesticide products, EPA had issued only 182 interim reregistration standards. EPA was on a schedule to issue approximately 25 new reregistration standards each year.

The General Accounting Office (GAO) reviewed the EPA reregistration effort and determined that EPA would not complete the reregistration process until the year 2024.

Congress determined that this schedule was unacceptable and enacted the FIFRA '88 amendments. There are several interesting things to note about these amendments. Because they were viewed as technical regulatory matters affecting how data would be supplied to the EPA, the legislative debate primarily involved the agency and the pesticide manufacturers.

The 1988 amendments were directed at accelerating the reregistration process. It was intended that this process be completed by 1997, some 27 years before EPA had been scheduled to complete it.

The schedules set by FIFRA '88 were extremely tight. Congress' intent was to take the delay out of the process, consequently, there is not a great deal of flexibility built into the process.

Why was FIFRA '88 so important to the agricultural community and minor users in particular? Because it would impact the continued availability of crop protection tools. This, in turn, significantly impacts a farmer's ability to economically grow and market a crop and ultimately affects the availability, variety, cost and quality of food for consumers.

With the passage of FIFRA '88, pesticide manufacturers had two immediate concerns -- capital outlays and personnel.

Registrants found that FIFRA '88 meant a compression in the time they had to develop data to support all the uses on their labels. A company had to face the prospect that, for example, if it had 10 products in its marketing line, the costs of reregistration could be several million dollars each year. The reaction of companies has been that they simply could not afford the outlays necessary to protect all chemicals and all uses in a compressed time frame. Choices had to be made.

The companies were also concerned from a personnel perspective. Companies submitting their products for reregistration wanted to be certain that any studies performed would not have to be repeated. This included ensuring that there was adequate supervision of the studies. This meant increased demands on company personnel and a need to determine whether all uses being maintained were essential to the business of the manufacturer. There was also insufficient laboratory space, analytical equipment, and field testing facilities available to do all of the required work.

In response to FIFRA '88, some registrants cancelled a number of pesticide uses outright. Others chose, for economic reasons, not to indicate immediately their decision to eliminate uses. Some simply did not know if they could provide the necessary data and simply indicated preliminary support for keeping the product.

Not only have the registrants faced hard choices relative to the reregistration of their products, but EPA has also had to focus resources and personnel into the reregistration process. The result has been that as products are dropped from the reregistration efforts, the economic barriers against minor uses for initial registration have also resulted in the lack of new uses. As we move further into the mandated deadline for data review decisions on active ingredients subject to reregistration, the problem has become more attenuated. Budget constraints have further reduced the ability of EPA to meet the existing time schedules.

As a response to the increasing loss of valuable crop protection tools, a broad coalition of farmers and farmer representatives met at the offices of United Fresh Fruit and Vegetable Association on September 17, 1991 and began to develop specific legislative and administrative solutions. Thus was formed the Minor Crop Farmer Alliance (MCFA).

Its members concluded that there was no silver bullet solution but a combination of legislative and regulatory remedies, along with increased minor crop program resources, could ease the problem. The Alliance agreed that the minor crop issue would be its sole objective. When the overall minor crop proposal is enacted and properly implemented, the Alliance will disband. Attached to this statement is a list of the current MCFA, a list which is growing rapidly.

The Alliance first recommends that the Congress enact certain amendments to FIFRA. These amendments would better define minor crops, provide incentives and remove impediments in the current law which adversely affect minor use registration and reregistration. Initial draft options were provided to Congressional committee and subcommittee staff.

In general, the Alliance proposed to address the problem in the following manner:

1. Provide incentives to chemical companies to continue to register and reregister safe chemicals for minor uses;
2. Provide incentives and resources to the EPA and the USDA to assist in registering and reregistering minor use chemicals; and
3. Provide necessary resources to USDA to assist minor crops. This will be accomplished by accelerating the development of better crop protection tools, either chemical or non-chemical, as well as assuring more focused research on minor crop issues.

After much give and take initial legislation was introduced during the last Congress and after further discussion and revisions, H.R. 967 was introduced February 18, 1993.

Summary of Amendments Which Are Included In H.R. 967 Introduced by Chairman de la Garza, Along With Mr. Stenholm, Roberts, Smith and Over 85 Other Cosponsors.

First, there is a need to provide a minor crop definition which would trigger certain actions by the EPA, USDA and the registrant. A minor use would be defined as the use of a pesticide on an animal, on a commercial agricultural crop or site, or for the protection of public health where:

1. The EPA Administrator, in consultation with the Secretary of Agriculture, determines that, based on information provided by an applicant, the use does not provide sufficient economic incentive to support the initial registration or continuing registration of a pesticide for such use; and
2. The EPA Administrator has not determined that, based on existing data, such use presents a risk of an unreasonable adverse effect on the environment.

We believe that this definition gives the EPA sufficient guidance in making regulatory decisions affecting minor crops. The Alliance members want to stress that the administrator continues to have authority to determine whether a particular pesticide or use presents an unreasonable adverse effect to the environment.

It should be noted that the above definitions are merely threshold economic criteria for minor use eligibility. They do not automatically qualify a use for special consideration. In consideration of special treatment, the overriding concerns should be protection of the consumer and the environment. The Congress should expect EPA, in reviewing the application, to consult USDA and to also review historical data in making an appropriate determination.

Our definition envisions a situation where the profit margin for the pesticide for that use is relatively small and the testing requirements associated with the use are relatively expensive. A situation could also arise where IPM Programs allow for treatment of a crop much less often than currently necessary, thus substantially reducing profits to registrants. The farmer should not be penalized for adopting IPM practices. If, upon review, EPA is satisfied that such information substantiates that sufficient economic incentive does not exist to support the use, EPA shall designate such use as a minor use under the definition. A similar review is currently conducted by EPA when it considers requests for low volume waivers of data requirements.

Second. Registrants would be provided an additional ten years of exclusive use of data which relates solely to supporting a minor use.

This amendment is intended to provide an incentive to registrants to maintain and expand minor uses. By providing for an additional 10-year period of exclusive use for data which solely supports a minor use, we expect that registrants will seek or maintain additional minor uses. This provision would create a 10-year exclusive use period for data submitted by a registrant which is not now entitled to exclusive use under existing § 3(c)(1)(F)(i), such as data submitted to support the reregistration, for a minor use, of an active ingredient. For

data which are already entitled to a period of exclusive use under existing § 3(c)(1)(F)(i), this provision would extend the exclusive use period. Thus, for example, if a new active ingredient was originally registered by the Administrator in 1991, and the registrant submitted data related solely to a minor use of the pesticide in 1996, the period for exclusive use of such minor use data would not expire, as under existing law in 2001, but instead would be extended until 2006, i.e., ten (10) years after the date of submission of the solely minor use data. Data which pertain to both major uses and minor uses of a product (such as basic toxicology data) would not be entitled to any exclusive use beyond that provided under current law. Further, if a registrant, for whatever reason, decided to voluntarily cancel the minor use registration, if the proposed legislation were adopted, the registrant could not maintain exclusive use of the minor use data beyond the time period currently provided under FIFRA. Instead, such data would only be entitled to whatever remaining exclusive use period that currently exists under FIFRA. If no such time period exists, the data would be available to other applicants in seeking a registration for the relevant minor use, subject to the current data compensation provisions.

Third. The EPA would be instructed to expeditiously review and act on, within six months of submission, applications for new chemicals solely that are: 1) for minor use or 2) for major uses that are submitted with significant minor uses. Significant minor uses means three or more uses for every non-minor use, a replacement for any use canceled in the preceding five years or a minor use which would replace one being issued under an emergency exemption under Section 18.

We recognize that the EPA has committed to review applications for all new chemicals within one year of submission. We realize that if the EPA does not devote additional resources to new chemical review, requiring expedited review of minor use new chemicals will delay review of those new chemicals which did not contain significant minor uses. It is not intended, however, that EPA should divert resources from reregistration efforts in order to expedite review of minor use new chemicals. We anticipate that providing for an expedited review of minor uses, while slowing down the review for those applications which do not contain minor uses, will encourage applicants to include significant minor uses in their initial applications for registration of active ingredients.

Fourth. We suggest that if a pesticide is being reregistered for minor uses as well as other uses, the EPA should be authorized to extend the deadline up to two years for the production of residue chemistry data required solely to support a minor use of a pesticide -- provided that the registrant is providing data to support the other major uses of the pesticide.

The purpose of this amendment is to provide an incentive to registrants to maintain and reregister minor uses. By extending the specified deadlines for submissions of studies which relate solely to such minor uses, the amendments should reduce the economic impacts upon the registrant of providing such data and should also allow a better-phased administration of such testing requirements. The extensions would apply only in those situations in which the registrant either has already produced, or is producing according to the EPA deadline requirements, data necessary to support the other uses of such pesticide. Thus, the Administrator will be receiving within the normal deadlines currently specified in the statute and the EPA's regulations, the basic toxicological, environmental fate, and ecological effects information regarding the pesticide. If the Administrator determines, based upon such core information, that continued use of the pesticide for the minor use may present unreasonable adverse effects, or, if the Administrator determines that the core information is not being provided within the normal deadline specified in the statute, the Administrator is authorized to deny or revoke the extension of time for the minor use data. The deadline extensions would require an application for extension by the registrant. In applying for such an extension, the registrant would be expected to submit a schedule, including interim deadline dates, to insure that the data would be submitted to EPA by the new requested deadline. The Administrator would be expected to track, and announce to the public, the progress of the development of such data to insure that the schedule is met by the registrant. If the data are not being developed, the Administrator would be expected to take appropriate regulatory action. We intend that such deadline extensions would be continued only to the extent that the registrant was making clear commitments and good faith efforts to produce the required data and the Administrator has determined that such extensions would not significantly delay the schedule for issuing a reregistration eligibility determination. Such an extension may also be revoked if the Administrator receives data sufficient to determine that an unreasonable adverse effect may exist involving the minor use. We intend that the public, including user groups, would be informed as rapidly as possible whenever the EPA has reason to believe that the data are not being generated by the registrant.

The Congress is aware that pesticide registrants are anxious to have their products reregistered. We are concerned that if the extension of the deadlines for minor use data would delay the re-registration of the pesticides, registrants may not be willing to seek such extensions, but may instead drop the relevant minor use registrations. Thus, this Amendment would clearly allow and require the EPA to reregister pesticides if the only data otherwise preventing reregistration are the data for which an extension has been granted pursuant to this provision.

Fifth. A temporary extension, rather than immediate suspension or cancellation, would be provided for a minor use registration that is being voluntarily dropped by the registrant. This would be contingent on the registrant providing data in a timely fashion for the reregistration of other uses of the pesticide.

Despite the other incentives provided, there is still concern that registrants may determine not to support certain minor uses. In such cases, we believe it is appropriate to provide a transition period before such minor uses are voluntarily canceled or suspended. Such a transition period will allow farmers to develop alternative crop protection techniques and also to allow time for registrants to register alternative pesticides for such minor uses. Such extensions would be available only when the registrant has provided or is providing the basic data regarding the pesticide in order to support other uses. The registrant must also agree to continue the minor use for such period. The amendment also would authorize the Administrator to restrict or eliminate this transition period in situations where the Administrator believes that continued use of the pesticide for such minor use would present unreasonable adverse effects to the environment.

Sixth. EPA would be required to utilize its authority to grant conditional registrations of a pesticide when the use would not significantly increase the risk of any unreasonable adverse effect on the environment or would not meet or exceed risk criteria for human dietary exposure.

The existing Section 3(c)(7)(B) of FIFRA allows the Administrator to conditionally amend the registration of a pesticide to permit additional uses even if the data concerning the pesticide are insufficient to support an unconditional amendment. The Administrator must determine that such a conditional amendment would not significantly increase the risk of any unreasonable adverse effect on the environment. There is concern that the Administrator has not taken advantage of this authority to allow sufficient conditional registrations for new minor uses. We believe that the Administrator should grant conditional registrations for new minor uses even when there are outstanding data requirements if the incremental risk that would be posed by the additional minor use would not be significant. Although EPA has allowed, as a policy, the conditional registration for minor uses which increase dietary risk by less than 1%, the Administrator has not developed any standards, criteria, or policy to allow additional minor uses when the risk issue of concern involves ecological effects, environmental fate or applicator exposure. We expect that the Administrator would develop criteria and standards through regulations to determine which incremental exposures would be considered significant and which would not. The Administrator would be expected to follow those regulatory criteria in making expeditious written

determinations regarding applications for conditional registration(s) of minor uses.

Seventh. We would propose that if a voluntary cancellation of a pesticide or use has occurred, supporting data from the previous registration should be available to support an application for a similar minor use of the same pesticide unless the Administrator determines that such minor use presents an unreasonable adverse effect on the environment.

Existing Section 6(f) of FIFRA provides for public notice of a proposed voluntary cancellation of a minor use and provides a mechanism to transfer such registration. There may be situations, however, in which the initial registrant who has proposed the voluntary cancellation, is unwilling, for whatever reason, to transfer its registration and may request voluntary cancellation of the registration. Currently, if such voluntary cancellation becomes effective prior to the time that a new applicant has obtained a registration for a similar chemical (and a similar use), the new application is treated as an application for registration of a new chemical, thus requiring a complete and full data base before the new registration will be granted by the EPA. If the voluntary cancellation had not taken place, however, under existing law, the new applicant would be required to submit (or to cite) only those data which supported the original registration. Any outstanding data requirements could be fulfilled after the registration has been issued. The purpose of this amendment is to allow the new applicant to receive a registration on the basis of the same (or similar) data which supported the original registration. There is concern, however, that the time period for filing an application to restore a minor use should not be open-ended. Therefore, we believe that the application for the registration of an identical or a substantially similar pesticide for a minor use should be filed not later than two (2) years after the voluntary cancellation has taken place.

Eighth. This section would establish a new activity as part of the Department's Minor Use Program. Specifically, a matching fund program would be authorized. Under this program, an entity such as an agricultural trade association, grower group, or individual grower, could request matching funds to develop data to support minor uses. Although traditional pesticide registrants such as chemical companies are eligible to participate in this program, it is intended that such registrants will have lower priority in regard to such funds as compared to grower groups and other entities who do not directly receive funds from the sale of product registered for minor uses. Once developed, these data could then be licensed to a third party for the purpose of seeking registrations and tolerances. Any fees that may be received by the Department from licensing the data would be remitted to a special revolving fund to assist in supporting this program.

Ninth. In addition to the coordination of existing programs within USDA and the establishment of a new revolving loan program, we must examine the operations of existing programs to ensure they are as responsive as possible to minor use concerns.

It is recommended that minor use programs within the USDA be coordinated. Historically, various agencies within the Department have been involved in issues and programs affecting the availability and development of crop protection tools and methods for minor uses. Because such activities have been dispersed throughout the Department, minor crop issues may not have been comprehensively addressed. By coordinating applicable program activities, the opportunity to address issues successfully can be enhanced. Further, efficiencies can be achieved.

One of the major concerns raised by members of the Alliance was the coordination and cooperation within USDA of program aspects dealing with the interests of our membership. The highly varied and diverse needs of the specialty crop and small acreage users are often overlooked in the implementation of other issues and initiatives.

We urge that a program be initiated at the highest level within the Department to ensure that the limited efforts of the minor crop program are not diluted or reduced in priority due to other activities.

The USDA program components as envisioned by the Alliance include:

- * Focusing USDA programs related to minor use under a designed coordinator.
- * Allowing for direct user group input and review of USDA minor use effort.
- * Establishing procedures to assure that minor uses are considered in major USDA areas, such as IPM, LISA, development of alternative crops, and environmental initiatives including development of Best Management Practices (BMPs), and groundwater or surface water controls.
- * Providing a point of contact for regulatory efforts, including the development of benefit data, that would impact minor uses at both the federal and state level, including communicating with EPA on matters of concern.
- * Assuring that adequate resources (both budgetary and human resources) for special projects of benefit to the minor use community are made available.

The Alliance recognizes and is extremely supportive of the Inter-Regional Project #4 (IR-4) of USDA. This program has not been given the priority it deserves for funding either at the federal or state level. Many of the members of the MCFA have worked cooperatively with IR-4 in the development of data necessary to support tolerances which can lead to food crop use registrations and several MCFA members are directly involved in IR-4's own commodity liaison committee. This program has also been invaluable in the expansion of uses of products registered for turf and ornamental uses.

The IR-4 program alone cannot fully meet the needs of the agricultural community but it is a very important component in the regulatory process. Over the past several years, IR-4 has received inadequate funds to deal with the ever increasing regulatory burden associated with residue and crop efficacy studies. As with EPA and its increased work load due to reregistration; IR-4 has had to deal with increased regulatory requirements under a decreasing fund scenario. In recognition of this fact, the Congress authorized funding of up to \$25M per year in the 1990 Farm Bill. Even if this funding level was available, the backlog of petitions already in place and the necessary sealing up of the laboratory facilities would not allow an immediate impact on the overall long term problems associated with minor uses of pesticides.

We feel that the MCFA legislative package will work in concert with the existing IR-4 structure to facilitate and streamline the data generation process to make IR-4's task as efficient as possible under the complex regulatory process dictated for pesticidal products.

The coordination of activities within USDA relative to minor use would only serve to enhance the status of this very important program.

In addition to a coordinated minor use program at USDA, a similar coordinated effort must exist at EPA.

EPA has recognized the need for consideration of the minor use community through the assignment of a minor use officer in the Registration Division. However, the Alliance has extreme concern over the present arrangement and its ability to meet the increased need both within the Agency and as it functions with the user community and registrants. It appears to the Alliance that an elevation in recognition of the importance of these activities and an increase in resources to meet the requirements of the proposed legislation is needed.

The EPA has had authority vested in the Administrator by FIFRA to provide criteria and policy direction to address many minor user concerns. However, there should be a clearly

designated minor use program. The major program components of the EPA Minor Use Program should include:

- * Designating a coordinator and staff to focus EPA activities on minor uses.
- * The coordinator and staff would provide cross-agency coordination and direct user community input into Agency processes that impact minor uses.
- * The coordinator and staff would ensure minor uses were considered as the Agency implemented major program changes or shifts in policy such as groundwater initiatives, Endangered Species Program, risk balancing and analysis, among others.
- * The coordinator and staff would serve as the point of contact for regulatory efforts at the federal and state levels.
- * The coordinator and staff would, among other things, track registration and reregistration activity for minor uses, provide a focal point for contact by the minor use community and serve as the coordinator for such programs as low volume waivers.
- * The coordinator and staff would also serve as liaison with the emergency response group within the registration division for minor uses.

CONCLUSION

We believe the above mentioned legislative and regulatory changes would be a positive step forward in addressing the minor use problem. Unless federal policy is changed, production agriculture in the United States will not have the necessary tools to bring a safe, abundant, varied and affordable supply of food and other farm products to American consumers. We urge that you give these proposals serious consideration. The Alliance looks forward to working with you and the Subcommittee.

(Attachment follows:)

MINOR CROP FARMER ALLIANCE

A-W Produce Co.
 A. Duda & Sons
 Alachua County Farm Bureau
 Alger Farms, Inc.
 American Assn. of Nurserymen
 American Corn Millers Federation
 American Dehydrated Onion and Garlic Association
 American Dry Pea and Lentil Association
 American Farm Bureau Federation
 American Frozen Food Institute
 American Seed Trade Assn.
 Atlantic County Board of Agriculture
 Aunt Jane Foods
 B&B Enterprises
 B&W Quality Growers, Inc.
 Bagley Produce Company, Inc.
 Baker County Farm Bureau
 Barrett Produce Company
 Bay County Farm Bureau
 Brevard County Farm Bureau
 Broward County Farm Bureau
 Calhoun County Farm Bureau
 Calif. Farm Bureau Federation
 Calif. Grape & Tree Fruit League
 California Avocado Comm.
 California Citrus Mutual
 California Cut Flower Commission
 California Pistachio Comm.
 California Strawberry Advisory Board
 California Table Grape Commission
 Carl Schuster Farms
 Center for Agriculture in the Environment
 American Farmland Trust
 Cherry Marketing Institute, Inc.
 Chiquita Brands, Inc.
 Chiquita Melon Packers
 Clay County Farm Bureau
 Columbia Basin Vegetable Seed Association
 Columbia County Farm Bureau
 Colville & Wilson, Inc.
 Consumers Produce Co., Inc.
 Cranberry Institute
 Dade County Farm Bureau
 DeBruyn Produce
 Del Monte Foods
 DeSoto-Charlotte Farm Bureau
 Donna Fruit Co., Inc.
 Dr. Stanley C. Hoyt
 EAK AG, Inc.
 Edinburg Citrus Association
 Elmore & Stahl, Inc.
 Escambia County Farm Bureau
 Florida Citrus Mutual
 Florida Citrus Packers
 Florida Citrus Production Managers Association
 Florida Farm Bureau Federation
 Florida Fruit & Vegetable Association
 Florida Nurserymen and Growers Association, Inc.
 Florida Sweet Corn Exchange
 Florida Tomato Exchange
 Food Marketing Institute
 Food Services of America, Inc.
 Frank J. Schuster Farming Co.
 Gilchrist County Farm Bureau
 Glad-A-Way Gardens
 Grower-Shipper Veg. Assn. of Central CA.
 Hardee County Farm Bureau
 Healds Valley Farms, Inc.
 Hendry-Glades Farm Bureau
 Hernando-Citrus Farm Bureau
 Highlands County Farm Bureau
 Hillsborough County Farm Bureau
 Holden Wallace, Inc.
 Idaho Association of Pea & Lentil Producers, Inc.
 Idaho Grower Shippers Association
 Idaho Potato Commission
 International Apple Institute
 Interstate Fruit & Vegetable Co., Inc.
 J&D Produce, Inc.
 J.S. McManus Produce Co., Inc.
 Jackson County Farm Bureau
 Krenmueller Farms
 L.M.B. Corporation
 Lafayette County Farm Bureau
 Lake County Farm Bureau
 Lee County Farm Bureau
 Leon County Farm Bureau
 Liberty County Farm Bureau
 Madison County Farm Bureau
 Manatee County Farm Bureau
 Marion County Farm Bureau
 Michigan Apple Committee
 Michigan Asparagus and Plum Advisory Boards
 Michigan Celery Promotion Cooperative
 Michigan Fresh Market Carrot Committee
 Michigan Onion Committee
 Michigan Potato Industry Commission
 Michigan Vegetable Council
 Nassau County Farm Bureau
 Nat'l Council of Farmer Cooperatives

MINOR CROP FARMER ALLIANCE

Nat. Assn. of State Depts. of Ag
 National Christmas Tree Association
 National Grape Cooperative Assn., Inc.
 National Onion Association
 National Potato Council
 National Watermelon Association
 New York State Vegetable Growers
 Association
 North American Strawberry Growers
 Assn.
 North Central Washington Fieldmen's
 Assoc.
 Northwest Food Processors Association
 Northwest Horticultural Council
 Okeechobee County Farm Bureau
 Orange County Farm Bureau
 Oregon Caneberry Commission
 Osceola County Farm Bureau
 Ostrom Farms
 Pacific Coast Canned Pear Service
 Pacific Seedmen's Assn.
 Palm Beach County Farm Bureau
 Palm Beach Wholesale Growers
 Palm Gardens, Inc.
 Pardi Produce, Inc.
 Pasco County Farm Bureau
 Pea and Lentil Prod., Inc.
 Pear Advisory Board
 Pecos Canteloupe Co., Inc.
 Pentagon Produce, Inc.
 Pinellas County Farm Bureau
 Plainview Produce, Inc.
 Plantation Produce Co.
 Polk County Farm Bureau
 Presidio Valley Farms, Inc.
 Produce Marketing Association
 Professional Plant Growers Association
 Rio Grande Okra Sales, Inc.
 Rio Grande Valley Chapter of Texas
 Agri-Women
 Robert Ruiz
 Roses, Inc.
 Santa Rosa County Farm Bureau
 Sarasota County Farm Bureau
 Seminole County Farm Bureau
 So. Carolina Tomato Assn.
 Society of American Florists
 South Bay Growers, Inc.
 Southland Care Co.
 St. Lucie County Farm Bureau
 Starr Produce Company
 State of New Hampshire Dept. of
 Agriculture
 Sumter County Farm Bureau
 Sunkist Growers, Inc.
 Suwannee County Farm Bureau
 Texana Pickle Producers, Inc.
 Texas Agri-Women, Inc.
 Texas Agri. Extension Service
 Texas Citrus & Vegetable Assn.
 Tree Top, Inc.
 U.S. Canola Association
 United Fresh Fruit & Veg. Assn.
 USA-Research Center
 Valley Fruit & Vegetable Company, Inc.
 Valley Onions, Inc.
 VM Distributing, Inc.
 Volusia County Farm Bureau
 Walker Bros. Produce Company
 Walton County Farm Bureau
 Washington Asparagus Commission
 Washington Association of Dry
 Washington Hop Commission
 Washington State Dept. of Agriculture
 Washington State Horticultural Assn.
 Western Growers Association
 Western Palm Beach Farm Bureau
 Wiesehan Farms, Inc.
 Yakima Pomological Club

Statement of William Hazeltnine, Ph.D., B.C.E., to the Subcommittee on Department Operations and Nutrition, of the House Committee on Agriculture, on H.R 1867 and the Need for Pesticides to Protect the Public's Health, June 10, 1993.

Mr. Chairman and members of the Subcommittee, I am here today representing the American Mosquito Control Association, a non-profit scientific and educational organization whose members are dedicated to protecting the public from insects and other pests and the diseases which those pests can transmit to mankind and domestic animals.

Our members have understood and practiced Integrated Pest Management (IPM) before that term became popular. As a consequence, we recognize the need for effective pesticides to use in our programs, which rely on prevention as well as control. Our Association members pioneered in the use of biological control through the manipulation of mosquito fish, and in physical control through water manipulation, as well as the safe and effective use of natural and synthetic pesticides. Our members continue to lead in this effort to provide comprehensive control of Public Health Pests.

However our ability to provide effective and acceptable programs is continuing to erode. Physical control involves reducing the water where mosquito larvae grow, which can put us in conflict with people who have wetland protection interests. We are now finding increasing concern over the potential harm which mosquito fish and other predators might have on endangered fish species. Pesticides for use in control are being continually reduced through economic (registration) constraints on the manufacturers; the public's fear of pesticides drives this restrictive action. Even mosquito control on Public Lands, such as wetland game refuges, is being resisted because of the reasoning that mosquito larvae are a food source for waterfowl and adult mosquitoes may be food for songbirds and bats.

It should be obvious that for good mosquito and other vector control programs to continue, professional Public Health Decision-makers need to have a wide array of choices available to them, so they can select the best material or method for use when control becomes necessary. If pesticides are not registered by the Federal Environmental Protection Agency (EPA) they are not going to be available for use to protect the Public's Health. While we continually look at a wide range of control alternatives, we recognize the need for effective pesticides which are registered and available for our use.

Physiological resistance to pesticides can best be forestalled, or prevented, by having a variety of pesticides to use, in sequence. When we are allowed to use only one or two pesticides in our comprehensive control programs, we know that this invites resistance to appear. Those who say that we should avoid pesticides because resistance may appear, are usually the same people who have never tried to make a control program work.

We recognize that this Subcommittee oversees the legislation which deals with pesticide regulation and use, and pesticide use is traditionally viewed as an agricultural production practice. We once again ask you to recognize that Health Professionals use pesticides for Public Health protection, and that the balancing of the risks and benefits required under the Federal Insecticide

Fungicide and Rodenticide Act (FIFRA) should recognize this difference. Our request is that this Subcommittee acknowledge that Public Health Pesticides should come under a separate set of risk/benefit considerations, and amend FIFRA to include a separate class of pesticide registration to accomplish this need.

Last year Congressman Herger along with a number of Cosponsors introduced H.R. 5110, which was titled the "Public Health Pesticide Protection Act of 1992." This Bill was intended to accommodate our needs. Chairman de la Garza and Cosponsors introduced H.R.4764, a broader Minor Use Pesticide Bill, and we were trying to get the Public Health minor use concept included in the broader bill, when the Session ended, without any Bill being passed.

We are back again, asking for recognition that our Public needs to have pesticides registered for public health uses. We need Public Health pesticides with their own specialized use directions and use limitations, which should be separate from the traditional use limitations which are part of agricultural use labels.

Congressman Dooley has introduced H.R.1867, with Congressman Herger as the Principal Cosponsor. This Bill contains almost the same language as last year's H.R.5110, and we urge you to give favorable consideration to this new Bill. H.R.1867 would make the following changes in FIFRA:

1. Define Minor Use, and include Public Health pesticide uses in the context of this definition.
2. Create a separate class of pesticide registration for Public Health pesticides with a risk/benefit balance which is separate from the balance which is utilized for agricultural pesticides.
3. Require that the EPA Administrator take into consideration "the differences in concept and usage" between agricultural, non-agricultural and Public Health pesticides.
4. Require consultation by the EPA Administrator with the Secretary of Health and Human Services on pesticides for Public Health use, similar to the existing consultation between EPA and USDA, and to prepare an annual report on vectors, diseases and pesticides used to control disease vectors.
5. Expedite registration of products necessary for Public Health protection.

In order to provide information for any of the Subcommittee Members who did not receive copies of our Association's earlier testimony (4/23/91), I am including copies of pertinent parts of it, with minor annotations to maintain its accuracy. Table 1. is corrected to show the mosquito control pesticides which are registered for our use in 1993 as well as in 1991. The 1993 list is considerably shorter than the 1991 list, which illustrates the way our available pesticides are being decreased.

Also included with our testimony are a few pages from a book written for The Institute of Medicine, and published by the National Academy Press in 1992. The Book's Title is "Emerging Infections: Microbial Threats to Health in the United States." Page 163 begins a section on Vector Control and the recommendation of this committee reads:

Fungicide and Rodenticide Act (FIFRA) should recognize this difference. Our request is that this Subcommittee acknowledge that Public Health Pesticides should come under a separate set of risk/benefit considerations, and amend FIFRA to include a separate class of pesticide registration to accomplish this need.

Last year Congressman Herger along with a number of Cosponsors introduced H.R. 5110, which was titled the "Public Health Pesticide Protection Act of 1992." This Bill was intended to accommodate our needs. Chairman de la Garza and Cosponsors introduced H.R.4764, a broader Minor Use Pesticide Bill, and we were trying to get the Public Health minor use concept included in the broader bill, when the Session ended, without any Bill being passed.

We are back again, asking for recognition that our Public needs to have pesticides registered for public health uses. We need Public Health pesticides with their own specialized use directions and use limitations, which should be separate from the traditional use limitations which are part of agricultural use labels.

Congressman Dooley has introduced H.R.1867, with Congressman Herger as the Principal Cosponsor. This Bill contains almost the same language as last year's H.R.5110, and we urge you to give favorable consideration to this new Bill. H.R.1867 would make the following changes in FIFRA:

1. Define Minor Use, and include Public Health pesticide uses in the context of this definition.
2. Create a separate class of pesticide registration for Public Health pesticides with a risk/benefit balance which is separate from the balance which is utilized for agricultural pesticides.
3. Require that the EPA Administrator take into consideration "the differences in concept and usage" between agricultural, non-agricultural and Public Health pesticides.
4. Require consultation by the EPA Administrator with the Secretary of Health and Human Services on pesticides for Public Health use, similar to the existing consultation between EPA and USDA, and to prepare an annual report on vectors, diseases and pesticides used to control disease vectors.
5. Expedite registration of products necessary for Public Health protection.

In order to provide information for any of the Subcommittee Members who did not receive copies of our Association's earlier testimony (4/23/91), I am including copies of pertinent parts of it, with minor annotations to maintain its accuracy. Table 1. is corrected to show the mosquito control pesticides which are registered for our use in 1993 as well as in 1991. The 1993 list is considerably shorter than the 1991 list, which illustrates the way our available pesticides are being decreased.

Also included with our testimony are a few pages from a book written for The Institute of Medicine, and published by the National Academy Press in 1992. The Book's Title is "Emerging Infections: Microbial Threats to Health in the United States." Page 163 begins a section on Vector Control and the recommendation of this committee reads:

"The committee recommends that the Environmental Protection Agency develop and implement alternative, expedited procedures for the licensing of pesticides for use in vector-borne disease emergencies. These procedures would include a means for stockpiling designated pesticides for such use."

Another recommendation on page 167 concludes this section on Vector Control by saying:

"The committee recommends that additional priority and funding be afforded efforts to develop pesticides (and effective modes of application) and other measures for public health use in suppressing vector-borne infectious diseases."

Those of us who are trying to practice Vector Control appreciate this recognition of the need for the legislative proposals we have been advocating, and we ask this Subcommittee to support the Institute of Medicine's recommendations by acting favorably on H.R.1867, which is before you.

There are some other issues which we hope can be addressed in your general legislation. These include:

1. Residue tolerances need to be uniform in all 50 States. The issue of residue tolerances should also recognize the need for keeping the standards reasonable. The recent proposal of EPA to establish di minimus tolerances in cases where amounts of pesticide residues are so low that they are insignificant should be legislatively supported. This would help to relieve a problem for us where we do NOT treat crops, but rather we may treat the water under the crop or the air around it for disease vectors. The doses of pesticides which we use are so much lower than those used for crop production that there needs to be a different standard established for our practices which will allow our control of disease vectors without having to expend the multiple millions of dollars doing studies when the amount of residue which we may create is insignificant.

2. There should be a measure of Federal Preemption on pesticide use restrictions. The Interstate Commerce basis for National pesticide registration should extend to the authority to use pesticides for Health Protection wherever they are necessary. Mosquitoes and other Vectors do not recognize political boundaries, and it makes no sense to be allowed to apply a pesticide up to the edge of a town or city, and not be able to apply the same material to control the same vectors across some imaginary boundary line. Similarly, Vectors being produced inside a "no spray" zone can fly out to infect people outside that zone, and Control Agencies would not be able to treat that breeding place (a Public Nuisance in many States) under a "no spray" limitation. Individual's rights are worthy of protection, but the rights of their neighbors must also be protected. When the issue is protection from Disease Vectors, the rights of the individuals to have disease protection should be given some added consideration.

Safety decisions on pesticide use and the decision of how and when that pesticide may be safely used has already been given to the Federal EPA. If there are new valid safety concerns, EPA has the authority to require a product's registration to be changed to meet this need.

3. Besides protecting humans from disease, a new area of concern involves the potential need of pesticides to protect animals which have been declared to be Rare or Endangered under the Endangered Species Act. Evidence is emerging to show that some of these endangered birds and mammals are subject to some of the same virus diseases which cause diseases in humans and which are transmitted by

insect and related Vectors. Some test results suggest that certain animals may even have become scarce because of insect vectored diseases.

A famous example of loss of Endangered birds involves the captive breeding population of Whooping Cranes where a considerable part of the known birds died from Eastern Equine Encephalitis (EEE) at the Pautextent Wildlife Station in Maryland in 1984. This is the same virus that was found in 1992 (last year) in 14% of the collections of the Imported Asian Tiger Mosquitoes collected in Polk County Florida, during an epidemic of EEE. At present, all the Whooping Cranes are vaccinated, but any of the young birds born in the wild will be susceptible. The virus is passed from bird to bird (which may also include song and wetland birds) in the wild by mosquitoes, and the only way to be sure the virus is not transmitted to these susceptible birds is to control the mosquito vector. Obviously effective insecticides are part of any comprehensive Vector Control Program, even in areas where rare or endangered wildlife may exist.

We are constantly told about the potential adverse impacts of pesticides on wildlife, but there is little if any recognition of the problems of wildlife which may be relieved by these same pesticides. Game birds and mammals are subject to a wide variety of insect vectored diseases which might be reduced by appropriate pesticide use. A good example of impacts on game birds is the periodic epidemics of EEE in pheasants and in the Midwest, where whole flocks can be wiped out. Only mosquito control can prevent these losses.

Other Endangered or Threatened Species for which there is evidence to suggest insect vectored virus diseases include Sand Hill Cranes, Kangaroo Rats, Harvest Mice, Cotton Rats, Tri-Colored Blackbirds, Big Horn Sheep and Bald Eagles. It is important to keep in mind that this evidence is mostly from incidental observations. Only the Whooping Crane work and vaccine use was the result of research directed at understanding the cause of mortality on a small breeding population. The rest of the data was from research aimed at finding the reservoirs of viruses which may cause disease in humans, or livestock such as horses and sheep.

"Fresno" and other species of Endangered Kangaroo Rats were used as test animals for virus disease research before they were listed, and they are extremely susceptible to Western Equine Encephalitis(WEE). It is interesting to observe that the kind of habitat which is used by many species of Kangaroo Rats in Central California are of low agricultural value, and it is common to have artificially flooded Duck Hunting Clubs surrounding the Rat's habitat. This creates ideal mosquito vector breeding areas as well as attractive sites for migratory birds which may be carrying viruses from other locations, resulting in high a disease risk for the endangered Rats.

We are constantly amazed at the way the benefits of pesticides are neglected in the rush to find any adverse effect which can be used as a reason to urge the ban of a pesticide.

We thank the Subcommittee members for the opportunity to testify about this very important subject, and we ask that you give serious consideration to our concerns for protection of the Public's Health with pesticides. We ask you to support H.R.1867 and when appropriate, to consider combining the Public Health Pesticide provisions into the Agricultural Minor Use Bill of Mr. de la Garza (HR 967), making the combined Bill a more comprehensive Minor Use Bill.

(Attachments follow:)

4/15/91

Statement of William Hazelstine, Ph.D., R.P.E., before the Department Operations, Research and Foreign Commerce Subcommittee of the House Committee on Agriculture, April 23, 1991.

I. Introduction

For the record, my name is William Haseltine, and I am the Manager - Environmentalist of the Butte County Mosquito Abatement District in California ("BCMAD"). The Board of Directors of the California Mosquito and Vector Control Association ("CMVCA") is composed of the President, Vice President, Secretary, Treasurer, and five members at large. The American Mosquito Control Association ("AMCA") have endorsed this statement. The AMCA is a non-profit scientific and educational association whose members represent mosquito abatement or mosquito control districts in the United States. On behalf of the BCMAD, CMVCA, and AMCA, I appreciate the opportunity to submit this statement.

My testimony has three principal purposes. First, I would like to explain what a mosquito abatement or mosquito control district is and what it does. Secondly, I would like to explain how the federal law that regulates the sale and use of pesticides, the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), affects the operations of a mosquito abatement district and how FIFRA could be amended to address the needs of mosquito control agencies. A third purpose of my testimony deals with the parts of the 1990 Clean Water Act that impose new requirements.

Our goal as health professionals is to protect the public by preventing the annoyance as well as the diseases which are transmitted by mosquitoes and other vectors (1). I emphasize the word "preventing" because that is

1/ There are approximately fifty diseases that are transmitted by insects or other arthropods. It should also be noted that the term vector includes biting and stinging insects, spiders, ticks mites, and also rats. Lyme ticks for example are vectors of Lyme Disease which also has unfortunately become more prominent recently. Some of our ANCA members are conducting research on this vector.

our mission. Perhaps we have been too successful up to this time in preventing insect transmitted diseases, because it is not until an epidemic such as the encephalitis cases in Florida and the Northeastern U.S. this past year, that our services are again recognized and strongly supported. When

we are successful in keeping these pests and their diseases controlled, recognition and public support fades.

Until recently, there has been a fair number of agricultural chemicals which could be adapted for our needs, and the registration system has allowed our uses of these products. However, the increased emphasis on risks of pesticides, along with the general fear of technology has seriously damaged our ability to use modern technology to benefit people.

We believe there is a continuing need to protect people from the environment as well as to protect the environment from people.

We would like to suggest that FIFRA was drafted by Congress in 1972 first and foremost for the purpose of regulating agricultural pesticides. Likewise, the U.S. Environmental Protection Agency ("EPA") has administered FIFRA principally from this same agricultural perspective. FIFRA is logical since agriculture accounts for the greatest pesticide use in this country and provides the greatest opportunity for significant human and environmental exposure to pesticides.

While we are appreciative of this fact, our agencies and the public we serve would benefit if FIFRA were amended to address the needs of mosquito control (vector control). First, we believe that FIFRA should create a special use category for public health pesticides.¹ Second, FIFRA's definition of "unreasonable adverse effects" should be made more stringent to ensure that pesticides should be made available to mosquito control agencies. Third, FIFRA's risks and benefits of public health pesticides separately from the risks and benefits of traditional (e.g. agricultural and household) pesticides. Third, since FIFRA requires the Administrator to confer with the Secretary of Agriculture when he proposes to regulate agricultural use pesticides, we believe it is only logical and consistent that the Administrator should also confer with the Secretary of Health and Human Services (HHS) when regulating public health pesticides. Fourth, we think reregistration requirements for public health pesticides should be considered apart from agricultural uses once developed by EPA after conferring with the USPHS. Finally, the IR-4 program should be expanded to include authority for assistance and funding for mosquito control programs. Finally, the Administrator should allow public funding of residues testing for mosquito control products.

It is interesting to consider the National Environmental Policy Act (NEPA) and to observe that two of the 5 policy goals seems to require risk-benefit balancing similar to those required in PIPRA. NEPA instructs all federal agencies to consider ways to:

- (2) assure for all Americans safe, healthful, productive, and esthetically and culturally pleasing surroundings;
- (3) attain the widest range of beneficial uses of the land, water, and air, and the highest conservation of health or safety, or other undesirable and unintended consequences; (emphasis added)

While not addressing pesticide uses specifically, this policy language does place human health protection in a preferential position. The use of pesticides is at times the best way to allow the enjoyment of the natural environment.

II. Mosquito Control

In California and in many other States, mosquito control agencies operate under, and are expressly authorized by State law. A district may comprise one or more counties, cities or operate as separate agencies of local government. In California and in most States, mosquito abatement districts may levy assessments on landowners to pay for their operations.

The statutory responsibility of mosquito control districts is usually to prevent the annoyance, as well as diseases (such as the recent unfortunate outbreaks of virus encephalitis in Florida and the Northeast) transmitted by mosquitoes and their vectors. Consequently, we view ourselves as health care providers. Mosquitoes breed in standing water -- environments that by their nature are sensitive and subject to close public scrutiny -- we are called upon to treat aquatic environments, including wetlands, tidal marshes and adjoining lands with pesticides. Our public health mission is to prevent the fact that we must treat aquatic environments with pesticides. We must care for our public health mission as well as our responsibilities to care for the natural environment.

Mosquito control should not be confused with eradication. A district is keeping a mosquito population below a threshold level. We are not preventing mosquito eating fish, and we would like to be able to reduce mosquito populations as another way to prevent breeding. We sample mosquito populations by various methods which include (1) dipping and counting larvae in water, (2) traps of various sorts which collect adults, and (3) actually counting the number of mosquitoes that feed and feed on us, in a set period of time. When the number exceeds the threshold, we need to have and be able to apply an effective pesticide. This is the way integrated pest management (IPM) works. We use a variety of application techniques, including aircraft, truck

mounted and hand-held sprayers. Obviously we must have effective pesticides which are appropriately used and applied in a safe manner. The more choices we have, the better we can make IPM work the way it was intended.

The table below will give you some idea of the limited number of pesticides which are still available for mosquito control, and the doses we use.

As you can see and perhaps contrary to popular belief, we do not have a wide variety of pesticides from which to choose. Compared to the many products still registered for agricultural use, relatively few pesticides are registered for mosquito and other vector control. Furthermore, the use of pesticides in the control of mosquitoes and a pesticide for mosquito control use, we face the prospect of losing more of these few remaining registered products in the near future. To avoid insect resistance and tailor the control method to the problem, public health programs need a variety of products from which to choose. Second, it should be noted that the rates at which we apply these pesticides are significantly below those rates which are used to control agricultural pests. And, as we hope you can appreciate, we do not apply products indiscriminately. We apply them only when the data indicates that populations are reaching levels that should be controlled.

III. FIPRA and Mosquito Control

A. Need to Define Minor Use, to Include Public Health

One compelling need is to define "minor use", and we recommend including a specific reference to public health use, in addition to minor agricultural use.

We suggest that the definition should read:

(th) MINOR USE. -- The term "minor use" means the total anticipated small volume use of any pesticide for the control of insects, mites, or other pests on a group of pests, which by itself would not economically justify a fully separate pesticide registration. Wherever a minor use is designated in this Act for Agricultural Crop production or Agricultural uses, that term shall also be understood to include any use intended to protect domestic animals from insect pests or diseases which such pests may transmit to man or domestic animals.

B. Creating a "Public Health Use" Category, and FIFRA's Definition of "Unreasonable Adverse Effects"

As the committee is aware, FIFRA regulates the sale and use of all pesticides. The registration, use (classification, reregistration, and deregistration (cancellation/suspension) provisions of FIFRA all use the same criteria. The standard that is, a pesticide may not be registered, reregistered, or have its use classified for restricted use or cancelled, unless it can do its job without causing unreasonable adverse effects. FIFRA defines "unreasonable adverse effects" to mean:

"any risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide."

As a practical matter, EPA does not consider a pesticide's benefits when it is registering, restricting or even reregistering a pesticide, but rather concentrates only on the risks. EPA will consider a pesticide's benefits only when it considers cancelling a pesticide from the market (e.g., when it is considering cancelling the pesticide). Moreover, when the Agency considers cancelling the registration of a pesticide, it considers the benefits of a pesticide in the narrow context of considering (a) whether there is an alternative registered pesticide that will perform the same function and (b) whether the increased costs of the alternative pesticide, availability of alternative pesticides sounds to us like the use of "essentiality" which is prohibited in Section 3(c)(5) of FIFRA, and which is antagonistic to the requirements of Section 28(c) of FIFRA, because Integrated Pest Management is the choice of control options available to the expert in the field.

We respectfully submit that more attention should be required of EPA when considering the benefits, and then the relative risks of pesticides used in public health programs. EPA should take the case of public health pesticides as an example. In the case of public health pesticides, the costs of the alternatives to repeat. We believe that FIFRA should be amended to recognize the category of pesticides called "public health pesticides". When considering any regulatory action affecting a public health pesticide, EPA should be required to consult with public health officials, and then with the Agency and then with the public health officials. The Agency should be required to be controlled by the pesticide and the relative risks of the pesticide under regulatory examination compared to the risks of any disease transmitted by those vectors and (3) the efficacy and costs of any alternatives, avoiding any consideration of essentiality.

This page amended to include 1993 Data.

Table 1 - Pesticides Used for Mosquito Control, 1991

Adulticides		
Trade Name	Active Ingredient	Application rate/acre
1. Cythion	Malathion	1.0 - 4.0 oz.
2. Scourge	Resmethrin	0.1 - 0.6 oz.
3. Dibrom	Naled	0.5 - 1.0 oz.
4. Baytex	Fenitron *	0.4 - 1.0 oz.
5. Premax	Permethrin ***	2.0 oz.
6. Various	Pyrethrin	0.1 - 0.3 oz.
7. Duraben	Chlorpyrifos	2.0 oz.
8. Baygon	Propoxur *	0.8 oz.
Larvicides		
1. Abate	Temephos	0.25 - 0.75 oz.
2. Baytex	Fenitron *	1.0 - 4.0 oz.
3. Duraben	Chlorpyrifos **	1.6 - 2.0 oz.
4. Cythion	Malathion	8.0 oz.
5. Parathion	Parathion	1.0 oz.
6. Various	Pyrethrin	0.25 oz.
7. Vectobac, Teknar	Bacillus thuringiensis, var israelensis	Various, based on active units
8, 7	Bacillus sphaericus	" " " "
9. Golden Bear Oil	----	2.0 - 3.0 gal.
10. Diesel Oil	----	2.0 - 3.0 gal.
11. Acoresur	Long chain alcohol	0.5 gal.
12. Dimilin	Diffubenzuron	0.4 oz.
13. Altoacid	Methoprene	3.0 - 4.0 oz.

Table 1A. Pesticides Registered and Available for Use in Mosquito Control, 1993

Adulticides		
Trade Name	Active Ingredient	Application rate/acre
1. Cythion	Malathion	1.0-4.0 oz.
2. Scourge	Resmethrin	0.1-0.6 oz.
3. Dibrom	Naled*	0.5-1.0 oz.
4. Premax	Permethrin*	2.0 oz.
5. Various	Pyrethrin	0.1-0.3 oz.
6. Duraben	Chlorpyrifos	2.0 oz.
Larvicides		
1. Abate	Temephos	0.25-0.75 oz.
2. Cythion	Malathion	8 oz.
3. Various	Pyrethrin	0.25 oz.
4. Vectobac, Teknar	Bacillus thuringiensis var. israelensis	Various, based on active units
5.	Bacillus sphaericus	" " " "
6. Golden Bear Oil	----	2.0-3.0 gal
7. Diesel Oil	----	2.0-3.0 gal
8. Dimilin	diffubenzuron	0.4 oz. (sand granule only)
9. Altoacid	methoprene	3.0-4.0 oz.

* Not Registered in all states. Permethrin is sold as an over-the-counter drug Nationwide for direct application to skin for mange mite control.

* Voluntary cancellation of all mosquito control uses.
 ** All aquatic uses removed from labeling.
 *** Not registered in all states.

As a first step in recognizing that public health pesticides are deserving of special regulatory treatment, the Administrator should request that the Administrator of EPA be amended to include the definition of "public health pesticide" which would be defined as "any pesticide registered for and used in public health programs for vector control."

We also suggest that the word "vector" be defined "as any animal capable of transmitting the agent of a human disease or capable of producing human discomfort or injury, including, but not limited to, mosquitoes, flies, other insects, ticks, mites and rats."

Secondly, we believe that the definition of "unreasonable adverse effects" (FIFRA section 2(bb)) should be amended to include the underscored language:

"The term unreasonable adverse effects on the environment" means any unreasonable risk to man or the environment, taking into account the economic, social and environmental costs and benefits of the use of any pesticide. The Administrator shall consider the risks and benefits of public health pesticides separate from the risks and benefits of other pesticides. In weighing any regulatory action concerning public health pesticides under this Act, the Administrator shall weigh any risks of the pesticide against the health risks such as the disease and discomfort to man caused by the vector to be controlled by the pesticide."

C. Other Conforming Changes

(1) Section 3(C)(2)(A) should also be amended to implement the new definition. We suggest the following underscored and lined through changes to accomplish this goal.

(A) The Administrator shall publish guidelines specifying the kinds of information which will be required to support the registration of pesticides. He shall revise such guidelines from time to time. If thereafter he requires any additional kind of information under subparagraph (B) of this paragraph, he shall permit sufficient time for applicants to obtain such additional information. The Administrator, in establishing standards for the registration of pesticides, shall be concerned with respect to minor use pesticides and shall be commensurate with the anticipated extent of use, pattern of use, the public health and agricultural need for such minor use, and the level and degree of potential exposure of beneficial or adverse effects on man and the

environment to the pesticide. The Administrator shall not require a person to submit, in relation to a registration or reregistration of a pesticide for minor ~~registered~~ use under this Act, any field residue data from a geographic area where the pesticide is not used for public health use. In development of these standards, the Administrator shall consider the economic factors of potential national volume of use, extent of distribution, and the impact of the cost of meeting the requirements on the incentives for any potential registrant to undertake the development of within 30 days after the Administrator registers a pesticide under this Act he shall make available to the public data called for in the registration statement together with such other scientific information as he deems relevant to his decision.

(2) FIFRA presently requires the Administrator of EPA to provide the Secretary of Agriculture with notice and to provide him an opportunity to comment on proposed regulations and pesticide cancellations. We think it is only logical that the Administrator should solicit the views of public health officials in the case of pesticides used in public health programs. To accomplish this, we propose that Section 21 be amended by adding a new subsection "b" and amending subsection "c" to read as follows: (d). The new subsection (b) should read:

(b) U.S. SURGEON GENERAL - For any public health pesticide, before publishing regulations under this subchapter, the Administrator shall solicit the views of the Surgeon General in the same manner and in the same manner and in accordance with similar procedures as described in Section 25(a), as those procedures apply to the Secretary of Agriculture.

(3) Section 6 of FIFRA should also be amended by adding a new subsection (b)(3) which would provide:

(b)(3) If a pesticide is registered or proposed for registration for public health use, the Administrator shall send the notice specified in subsection (b) to the Surgeon General for review. The Surgeon General shall comment in accordance with the procedures and standards of the Secretary of Agriculture and the Secretary of Agriculture in the case of agricultural pesticides.

(4) Finally, we suggest that Section 28 be amended to include public health interests in a cooperative effort with EPA by the addition of a new subsection (d), which would read:

(d) Public health pests. - The Administrator in coordination with the Secretary of Health and Human Services shall identify pests of significant public

health importance and in coordination and cooperation with the U.S. Public Health Service, and the use of safe and necessary use of chemical, biological and other methods to combat and control such pests of public health importance.

A copy of all proposed amendments is attached as Appendix A in mark-up form.

IV. Examples of Pesticide Use Problems Faced by Mosquito Control Agencies

Let me provide you some specific examples of the kinds of local problems we are facing, as we try to use pesticides to protect people from mosquitoes and other vectors. These examples are intended to demonstrate why the changes which we are proposing are reasonable and necessary.

(40)

1. This past year, one manufacturer voluntarily withdrew a product from the market, which we have depended on primarily for flood water mosquito control. The costs to produce the mass of data being required by EPA was the stated reason for voluntary cancellation. We used one of these products to control a vicious species of flood mosquitoes on almost all of our islands. These mosquitoes are part of reservoir cycle for two kinds of encephalitis. These same mosquitoes are a serious dis-ease problem for duck hunters and city people alike. The other one of these cancelled products is only used for mosquito and household insect control, at the requirement of State health officials. I am sure that the Federal Government would permit "minor" health protection use was only to the question. In the past, the State had allowed our use of these products, after preliminary residue levels were run and evaluated.

* 2. We use parathion at a dose rate of 1/10 pound of active ingredient per acre. This is a much lower dose than the amount generally needed for crop protection. While this product is still available, we have been told it is only a matter of time until it will be lost, despite the mosquito control and crop protection benefits. The issue is fear of human toxicity.

But consider these facts. One-tenth pound of anything spread over an acre of surface is essentially 1 milligram per square foot. As one essential doctor who has studied California Department of Health Services concluded, standing person occupies about 2 square feet of surface, so

* Parathion Registration now Cancelled.

if the entire dose we apply fell to earth and it all got on a person, and they ate it all, which is impossible, the dose would be about 1 milligram. But this is not true. Although there would not expect to see any signs or symptoms from this maximum possible 2 milligram exposure, because in earlier years, volunteer prisoners were fed daily doses of 3 milligrams (half again more than would 42 the maximum possible dose, based on our use) for 42 days. They had no depression or enzyme depression, which could be measured.

Obviously we do not directly treat people with this pesticide, but this evaluation shows the very small exposure risk from any inadvertent exposure of people to the pesticide. The EPA has also recognized that our applications should be exempt from worker reentry restrictions, because of our small doses, and the need to protect workers from mosquitoes. Therefore our use of parathion should not cause any unreasonable or significant health risk, particularly considering the health risk posed by the mosquito control, which this use provides.

3. We use natural pyrethrin, an extract of a Chrysanthemum like flower. This product has been used for over 100 years for insect control. The cost of this pesticide now runs about \$300 per pound, when we can get it. While it works at a very low dose, it is still expensive. In the early 1900s researchers found out that a synthetic chemical synergist could be used to make the pyrethrin work at a much lower dose, thus reducing the cost by the same factor of 5.

(990)

This past year, an organic almond grower in our District claimed we damaged his crop because we used a product near his land that contained pyrethrin. The grower claimed that the claim for loss was made only after the use of the synthetic chemical synergist near his almonds which were on the ground, waiting to be swept up and hulled. While the chemical was not applied to his land, apparently a use near his land was enough to damage his claim. The Certified Organic Growers Association (the National Organic Growers Association) stated that this synergist chemical could not be used on a crop, if it is to be called "certified organic".

4. Over the past years, researchers have found that a native fungus, *Beauveria gigasporium*, would kill the mosquito. The researchers, and developed agencies have evaluated this fungus, and developed

methods to grow it in the laboratory on artificial medium. The product could be used in the field in any way the virulent form could be produced for testing, and we could not produce enough infected mosquitoes for large scale field use.

The irony is that we can buy a small amount of a fungus from commercial sources to control the fungus in mosquitoes, take those insects and grow the mosquitoes to the field and use them to treat a breeding source, without any EPA oversight. However, once we grow this fungus in an artificial medium, we have a pesticide product which requires registration. We have to go through the EPA product registration process. The testing and field work necessary to support an application for registration has taken many years, even with the help at one time of the IR-4 program. The application for registration was filed by the California Department of Health Services in late 1967, and the product is still in the registration process. At the time we were informally advised to hire a Beltway Bandit (read consultant) if we wanted to speed up the registration process.

5. Diesel oil has historically been used for mosquito control, but when the 1972 Amendments to FIFRA were passed, it was required that the product be registered as an oil marketer to go through the Federal registration process for Diesel. At least one large marketer had registered his oil under California law before 1972, but that registration was allowed to lapse. With the present enforcement attention to minute details, we have encountered someone that used an unregistered product such as oil was a violation of law.

EPA, to the credit of their local enforcement people, decided that our use of diesel oil should be permitted to continue. California however, there required registration for Diesel. However, there was a registered, traditional larvicidal pesticide product which has label directions to use either oil or water as a diluent. However, oil alone works just as well, and use of the second pesticide product was only necessary to overcome a prosecutive problem. Avoiding that problem, the traditional pesticide at less than labeled rates, so we mix the oil with only enough of the traditional pesticide so it can be found, if tested, and we are legal. So in order to avoid a labeling violation, we have to use more pesticide than is necessary to kill the mosquito larvae.

Perhaps this was the kind of situation the Senate Committee contemplated when they said:

"It is not the intention of the Committee to prohibit any use which is in compliance with the Federal Insecticide, Fungicide, and Rodenticide Act, but the bill to assure that such use would not be prohibited, but concluded that this was a matter which would have to be left to the good sense of the Administrator, the manufacturers, and the users." (emphasis added)

6. The pesticide Dimilin (diflubenzuron) has an unusual way of killing insects and related animals; it acts by blocking the hardening of the external skeleton, during the molting or growth process. This selective way of acting shows it is not expected to cause problems with birds, which do not lay eggs and which are not expected to be exposed to safety to higher animals. It is an excellent selective mosquito control material, which was almost registered when increased data requirements were imposed. At the present time, due to lack of a residue tolerance on pasture grass, the only way we can use this chemical is to spray pastures and use that product to make our own granular formulations. Granules are supposed to fall past the plants, and go into the water, without leaving a residue on the plant materials. The extra work and inconvenience (added costs) has made this useful product unattractive.

Apparently this same active ingredient is registered for area wide Gypsy Moth control in the Eastern U.S.

7. The synthetic pyrethroid product Permethrin gives us a way to control adult mosquitoes. It also is a good material to kill and repel Lyme ticks, especially when applied to clothing. At the present time, we can buy a Federally registered product with directions for tick control, but in Nevada and not in California. This product is the kind of product that is needed by the States with a different requirement for labeling and registration than required under the Federal registration process. This problem was recognized and supposedly laid to rest when the Federal preemption language on labeling and packaging was included in Section 14 (b) of FIFRA. However, the packaging was the recognition that separate State registration and labeling requirements would interfere with Interstate Commerce.

*But the country recognizes
Afghanistan Distinct*

EMERGING INFECTIONS

Microbial Threats to Health in the United States

Joshua Lederberg, Robert E. Shope,
and Stanley C. Oaks, Jr., *Editors*

Committee on Emerging Microbial Threats to Health
Division of Health Sciences Policy
Division of International Health

INSTITUTE OF MEDICINE

NATIONAL ACADEMY PRESS
Washington, D.C. 1992

In temperate zones, epidemic onset of a newly emergent vector-borne disease occurs most often in the spring or summer, since both vector and pathogen depend on higher temperatures to maintain a rapid rate of reproduction. The spread of infection during the summer months may be rapid, particularly if humans are an effective source of vector infection or if the agent has become widespread in a nonhuman reservoir population. Thus, to be effective, vector control efforts must be launched shortly after the disease is first recognized or, ideally, before the disease is apparent.

For most vector-borne infectious diseases, the onset of winter dampens transmission or can even eliminate the vector or infectious agent. The exception is pathogens that can survive in humans for long periods and produce chronic infection (e.g., malaria and typhus). Vectors native to temperate areas, if introduced into new regions, may be able to survive at low temperatures, while those native to the tropics may not. In much of North America, cold weather is a second line of defense against most newly emerged or introduced pathogens that depend on vectors to be transmitted to humans. A sudden decrease in incidence of an unidentified disease at the start of winter may be the first epidemiological evidence that the disease is vectorborne.

VECTOR-CONTROL RESOURCES

North America has extensive vector-control resources. In fact, vector control is an essential part of environmental health programs in many communities. California's mosquito control, for example, covers most of the state and involves some 72 agencies with a 1991 budget of more than \$48.9 million for an area with a population of more than 20 million (California Mosquito and Vector Control Association, Inc., 1991). Statewide surveillance for mosquito-borne encephalitis, plague, malaria, and Lyme disease is coordinated by the California Department of Health Services.

There are approximately 1,000 additional regional and community vector-control and vector-surveillance programs in the United States and Canada (American Mosquito Control Association, 1991). Most of these programs are geared to protecting local populations from indigenous vector-borne diseases and arthropod pests. They may also provide an early line of defense against newly introduced or resurgent vector-borne diseases. In the United States, responsibility for organizing surveillance data and investigating epidemics of emerging vector-borne diseases, such as encephalitis, plague, and Lyme disease, rests with the CDC's Division of Vector-Borne Infectious Diseases in Fort Collins, Colorado.

The control methods used in a particular region depend on the vectors that are present and on what is known about their biology and behavior. Chemical and biological agents and environmental modification can be

used individually or together in an integrated control effort. Although many local and regional vector-control programs can effectively combat local and even regional outbreaks of vector-borne disease, they are not equipped to deal with outbreaks that are national in scope. For example, regional vector-control programs cannot declare a health emergency or bypass the many legal restrictions that now limit the use of certain pesticides that are potentially useful for vector-control efforts. That authority rests with health and environmental agencies at the state and federal levels.

PESTICIDES FOR VECTOR CONTROL

A growing problem in controlling vector-borne diseases is the diminishing supply of effective pesticides. Federal and state regulations increasingly restrict the use and supply of such chemicals, largely as a result of concerns over human health or environmental safety. All pesticides must be registered with the U.S. Environmental Protection Agency (EPA) before they can be offered for sale in the United States. A 1972 amendment to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), called for all pesticides to be re-registered by 1975 in order to meet new health and safety standards (Public Law No. 92-516). By 1986, only one of approximately 1,200 previously registered pesticides had met all of the re-registration requirements. A 1988 amendment to FIFRA moved the re-registration deadline to 1997, giving manufacturers additional time to locate or develop scientific data necessary for re-registration that were not in the original registration materials for their products. If adequate data are not submitted by the cut-off date, pesticide makers face the loss of registration (Moses, 1992).

Some manufacturers have chosen not to re-register their products because of the expense of gathering the required safety data. Partly as a result, many effective pesticides developed over the past 40 years to control agricultural pests and vectors of human disease are no longer available because their registrations have been canceled or suspended in the United States.

For example, malathion, a pesticide used worldwide for both agricultural and public health purposes, is currently registered in the United States but must be re-registered in accordance with the provisions of FIFRA. The manufacturer (American Cyanamid Corporation) has sold the rights to malathion to a Danish company, which may or may not apply for re-registration in the United States. Because malathion is an effective, relatively inexpensive broad-spectrum pesticide, a failure to re-register would be considerable cause for concern.

Pyrethrum, a plant product that has been used successfully to control adult vectors for many years, is currently being reviewed for its potential environmental and health hazards. This product is not produced in the

United States, and supply is often a problem. Nevertheless, its failure to be re-registered would be a serious loss to the vector-control armamentarium in this country.

In addition, the new registration frequently limits the circumstances under which products may be applied. In many instances, compounds that were once approved for pest-control applications are now restricted to certain narrow agricultural uses, such as for pest control in a single crop. The result is that many pesticides that might have been used to control emerging vector-borne diseases are either no longer registered or are not available in sufficient quantity.

In accordance with federal endangered species legislation, the EPA further restricts pesticide use through its Endangered Species Protection Plan. The plan prohibits the use of a wide range of pesticides within the habitat of any endangered species. Prohibitions extend in some cases to urban and suburban environments, in which outbreaks of vector-borne disease pose a particular threat. Efforts have been made to develop a workable, legal strategy for vector control in the event of a public health emergency. Specifically, EPA has developed an emergency exemption procedure in collaboration with the California Mosquito and Vector Control Association and the American Mosquito Control Association. The plan calls for specific steps to be followed when surveillance data suggest that the possibility of an outbreak of a vector-borne disease is great. After the local vector-control agency has determined a need to invoke the exemption, it must follow a 12-step procedure that includes review of the area for endangered species, consultation with the U.S. Fish and Wildlife Service (FWS), submission of a request for a public health exemption to the state public health agency or the CDC, a review and determination by the state agency or the CDC (which must be performed within 10 days if an emergency is anticipated or within 24 hours if the emergency is in progress), review and revision (if necessary) of the original plan and submission of a final plan to the state or the CDC, submission (within 15 days) by the CDC of a request to the EPA for an exemption, EPA consultation with the FWS, EPA approval or denial of the request (within 15 days), and, finally, implementation of the plan (B. Eldridge, Director, Mosquito Research Program, Department of Entomology, University of California at Davis, personal communication, 1992).

The committee recommends that the Environmental Protection Agency develop and implement alternative, expedited procedures for the licensing of pesticides for use in vector-borne infectious disease emergencies. These procedures would include a means for stockpiling designated pesticides for such use.

As with vaccines, there is little economic incentive for firms to develop new pesticides for public health use because such use makes up a very

small part of the pesticide market. The committee feels strongly, however, that pesticide development in this area needs to be given some priority. Pesticide development is now driven mainly by the demands of agriculture. Moreover, as pesticide development has become ever more specialized, there are fewer compounds available that have both agricultural and public health uses.

Agricultural applications account for about 75 percent of pesticide use in the United States. Approximately 407,000 tons of pesticide were used in 1987, of which about 89,500 tons were insecticides. Public health use accounts for about 10 percent of all pesticides globally; the major public health uses are for control of malaria, filariasis, schistosomiasis, onchocerciasis, and trypanosomiasis (Moses, 1992).

Dichlorodiphenyl trichloroethane (DDT), one of the most effective and economical pesticides ever developed, was first marketed in 1942, three years after Swiss chemist Paul Mueller discovered that the compound had insecticidal properties. In 1972, all agricultural use of DDT in the United States was banned because of its adverse environmental effects. Its use is now restricted by the EPA to public health emergencies, as defined under FIFRA. DDT is still used in many developing countries for public health purposes, particularly malaria control. Currently, aldrin, benzene hexachloride, chlordane, chlordimeform, DBCP, diazinon, dieldrin, dinoseb, ethylene dibromide, endrin, EPN, heptachlor, lindane, mirex, nitrofen (TOK), 2,4,5-T/silvex, and toxaphene also are banned, suspended, or severely restricted in their use as pesticides within the United States (Moses, 1992).

The use of insect growth regulators (so-called biorational or third-generation pesticides) to control vector populations is being investigated. These compounds affect certain biological processes of insects, such as metamorphosis, that are not present in mammals and other vertebrates. Biological control agents (the use of one organism to control another) are also considered biorational pesticides. Once licensed, many such materials will be used to control the immature stages of a number of insect vectors. They are likely to be of limited value as adulticides, however, since compounds used to control adult insects usually must produce mortality quickly. So far, only conventional broad-spectrum pesticides possess this characteristic. Resistance to biorational pesticides has recently been demonstrated in laboratory settings, even in the case of microbial pesticides.

The lack of a sufficient stockpile of effective pesticides, which might be required in the event of a major epidemic, continues to be a serious problem. The public health community has played a minor role in the formulation of pesticide use policy, which is mainly influenced by agricultural and environmental lobbying efforts. Until there are adequate alternative means for controlling disease-carrying vectors, it is critical that public health requirements for pesticides be considered when pesticide policy is being

debated. There may well be instances in which the limited application of pesticides, such as DDT, to deal with a public health emergency may be acceptable—as long as the overall burden on the environment is not excessive. The committee believes that the current EPA contingency plan that addresses this issue is ineffective; the approval process for emergency use of pesticides is so cumbersome that approval would likely come after the critical period in which application of the pesticide could avert the outbreak. Under emergency circumstances, a tradeoff must be made, so that the process can be more expedient.

Several arboviruses (St. Louis, western, and eastern equine encephalitis) are examples of diseases that could erupt suddenly into emergency proportions that might require pesticide use. These arboviruses are enzootic in North America and are maintained in a cycle of infection between wild birds and vector mosquitoes, with little or no transmission to humans. Periodically, however, excessive rain or snow, followed by high summer temperatures, favors the emergence of increased vector populations, which may lead to the rapid spread of infection to humans.

These events can occur in both urban and rural communities, and when they do, there is an immediate need to implement a control program. The primary goal at the onset of mosquito-borne disease epidemics is to eliminate the infective mosquitoes as quickly as possible. Transmission can only be stopped by the effective application of a pesticide that kills adult mosquitoes. A control program directed against the preadult aquatic and adult stages of the vector would not have an immediate effect on virus transmission but might be valuable for preventing a prolonged epidemic.

St. Louis encephalitis (SLE) exemplifies the above scenario. It has frequently reemerged as an epidemic infection in the United States (Monath, 1980), most recently in Florida and Texas in 1990 (Centers for Disease Control, 1990d). In 1986, an effort was made, in the middle of an epidemic in Dallas, Texas, to evaluate the effectiveness of controlling populations of adult mosquitoes that transmit this disease. There were 545 suspected and 145 confirmed cases of SLE in a period of a few weeks (Hopkins et al., 1975). In an eight-day period, 475,000 acres of the area were aerially sprayed with 12,000 gallons of malathion in an ultra-low-volume, high-concentration mist. Observations made before and after the application indicated that there was a significant reduction in the vector population and its infection rate. Few new cases were detected during the two to three weeks after the spraying. This is one of the few epidemics of a reemerging infection for which a study was conducted on its economic impact. It was estimated that the SLE outbreak cost the community \$796,500, of which almost \$200,000 was spent on vector control (Schwab, 1968). The economic and public health consequences would certainly have been greater had pesticides not been available.

Alternative strategies for the control of epidemics of SLE and western equine encephalitis are considered in detail elsewhere (Reeves and Milby, 1990). In the event of an epidemic caused by one of these enzootic viruses, the control of adult vectors is probably the best approach for stopping the spread of disease. To be successful, it has been estimated that pesticide application should achieve a 90 percent or greater reduction in the infected vector population (W. Reeves, Professor of Epidemiology Emeritus, School of Public Health, University of California at Berkeley, personal communication, 1992).

As in the drug-arena, resistance to pesticides can present serious problems to disease control. Mosquitoes, flies, and other disease-carrying insects have relatively short life cycles and produce many generations per year. This is a major factor in the development of pesticide resistance, and it is usually in these groups that resistance to a given chemical is seen. There are many strategies that can be used to delay or prevent pesticide resistance. So-called pesticide resistance management can include the rotation of chemicals, avoidance of sublethal doses, and the use of biodegradable materials. More research is needed, however, to hone the usefulness of these approaches.

The committee recommends that additional priority and funding be afforded efforts to develop pesticides (and effective modes of application) and other measures for public health use in suppressing vector-borne infectious diseases.

March 4, 1993

Wm. Hazeltine
119 Flying Cloud Drive
Oroville, CA 95965

Summary of Information on Aedes albopictus, the Asian Tiger Mosquito

This mosquito was imported to the United States from Asia. It was first found in Houston, Texas in August of 1985. It has since been intercepted in used tires coming into the U.S. from Japan and other Asian Countries.

Since its introduction, it has spread over the Southeastern United States, and as far North as Chicago, Illinois. This spread is attributed in large part to the shipment of used tires which may contain water and larvae or just the mosquito eggs, because this kind of mosquito can pass prolonged dry conditions in the egg stage. In addition to tires, this insect can breed in natural tree cavities, which may contain water for some part of the year.

While attempts are being made to discover natural control mechanisms to use against this mosquito in tire piles, the best control is (1) to eliminate the tires, which can be a serious economic disruption and frustrate recycling efforts, (2) store all tires under cover, which is expensive and probably would not work except in industrial areas, or (3) use pesticides for control of the adults and possibly the larvae. The problems with controlling the larvae in water in old tires is to find a way to get the pesticide to the problem areas hidden down in a pile of tires.

The trend to restrict and remove pesticides from the marketplace has seriously hurt the ability of Health Officials to control this mosquito, as well as other mosquitoes, ticks, fleas and other vectors of disease. We need pesticides to protect people and the human environment from serious disease and nuisances.

The Asian Tiger mosquitoes readily bite people, and can be a serious nuisance to anyone. Even more serious is the disease risks associated with this species. Up until a year ago, the Public Health authorities listed only the risks of Dengue plus Dengue Hemorrhagic Fever, and Yellow Fever as the major threats from this mosquito. Dengue is prevalent in Cuba and other Caribbean Areas, as well as in South America and Asia, and it is a very serious killer of infants in Asia. The Condition of Hemorrhagic Fever is where the extremities turn black because the virus causes the destruction of the blood capillaries.

A discovery made in 1992 shows that in mosquitoes collected in Polk County Florida, 14 % of the tested groups of mosquito as positive for Eastern Equine Encephalitis. This was during a human and horse epidemic there, in which there were 6 human cases and 178 horse cases. Laboratory studies have confirmed that this mosquito is an excellent potential vector for other virus diseases of humans as well, including St. Louis Encephalitis (active at Disney world a few years ago), Western Equine Encephalitis, La Cross Encephalitis and Yellow Fever. It is also an excellent vector of Dog Heartworm,

Members of the American Mosquito Control Association are happy to provide this information to you, and we are always ready to assist the personnel of the U.S. Public Health Service, Center for Disease Control in working toward better controls.

We desperately need assistance in the form of improved pesticide registration and availability of effective pesticides. This is the reason we have asked Congressmen Dooley and Herger to sponsor a Bill to amend the Federal Insecticide, Fungicide and Rodenticide Act, to add a section dealing with Public Health Pesticides. This bill will be introduced shortly.

DISTRIBUTION OF *AEDES ALBOPICTUS* IN THE UNITED STATES

The Asian Tiger Mosquito



1986



1988



1987



1991

WILLIAM HAZELTINE Ph.D., B.C.E.**Environmental Consultant****119 Flying Cloud Dr.
Oroville, CA. 95965****(916) 534-5629
Call for FAX connection**April 30, 1993
Revised May 27, 1993**MOSQUITOES, DISEASE AND ENDANGERED SPECIES****Introduction:**

There is a traditional belief in our society that pesticides are detrimental to wildlife. This belief is the result of many factors, but primarily it is because of the alliance of Sport Hunters, Wildlife and Environmental organizations. This belief is also the secondary result of the folklore which is being taught as scientific fact in our Elementary educational system.

The idea that pesticides are not natural, and therefore "they must be detrimental to nature or wildlife" is the non-logic being fostered to further this belief.

Yet pesticides were developed to control pests--those organisms which eat crops, damage health, or are in competition with people for living space. Within this concept, wildlife is in large part a food crop, as sportsmen (hunters or fishermen) tell us, and as such, wildlife for sport harvest should be protected from pests which reduce the yield or harvest.

Endangered Species as well as plentiful plant and animal species of "wildlife", are subject to attack by pests, just like any other organism. Endangered or threatened wildlife do not escape predators and parasites, which eat on or otherwise adversely impact them, the same way these predators and parasites impact any other organism.

Present evidence shows that at least one species of bird is extremely rare, and may yet become extinct, due to a virus disease which is only possible when mosquitoes carry or vector the virus from bird to bird. Kangaroo rats, while not as rare, are subject to other viruses that mosquitoes carry from wild birds to them. As more research is done, the expectation is that there will be many more species of endangered animals that will be found to be harmed by similar insect vectored viruses and other disease organisms.

Plants, whether rare or plentiful, are eaten by insects, and other animal species in the "food web", but only humans are expected to know which species are so rare that they should not be eaten or harmed. The use of pesticides to protect rare plants from predation would seem

appropriate, the same way we use pesticides to protect and increase the yield of plants for human or livestock consumption.

The Endangered Species Act calls for "Conservation" of rare species, which means doing whatever is necessary to increase their numbers. Surely protecting those rare species from disease and predation is appropriate, yet there is a strong prejudice against such protection, if it involves the use of pesticides or even alteration of wetlands. Such is the dilemma.

Origin of the Problem:

The years 1961-62 marked the first major outcry against the use of pesticides. Popular fiction told stories of birds dying in tremors, after ingesting food containing a popularly used pesticide. There had been isolated stories of wildlife "suffering" before that time, but after the Book Silent Spring, the stories were extensive. Many Organizations sprung up to build on the anti-pesticide feelings which they themselves helped to create. The "Scientific" leaders of these Tax Exempt Organizations even wrote their own literature, much of which was published in newspapers or marginally credible "Scientific Journals."

There were even incidents of citation webs, where author A suggested something might be correlated with some event; author B would cite author A to give the correlation support, then author A would cite B as having concluded that the event was fact. Remember that correlation does not prove cause and effect; it only says two events have occurred at the same time or in the same place.

There were some cases where the data was stretched to try and make it fit a conclusion which was not supported by the evidence. In short, science was abused for the sake of winning some public relations achievement. In science, the "whole truth concept" is supposed to be met at all times. Science is not a contest where different experts tell their own side or belief, with the public left to decide which one of these people is really an expert, or which one is believable.

During Earth Days (April 22, 1972 and later) the public and particularly students at colleges were subjected to all sorts of situations where they could demonstrate their beliefs, and do something about the environmental degradation alleged to be caused by chemicals and other causes. The movement was really aimed at stopping technology, with no thought about the benefits these technologies had produced. The affluent students were expected to demonstrate their faith in a "cause."

As Sol. Alinsky, the radical organizer said in one of

his self-help books, Rules for Radicals, "If the ends don't justify the means, what the hell does?"

Mosquito Disease transmission:

In order to understand the issue of damage to animals by viruses or other disease causing organisms carried or vectored by insects, it is necessary to understand some details of how such diseases organisms are transmitted.

In the case of malaria, the protozoan parasites must go through alternate hosts, in order to have natural transmission. The organism must have a vertebrate host and then a mosquito host or vector, and then go back into a vertebrate host. A necessary part of the life cycle occurs in each host. There is bird malaria, as well as malaria in mammals, and each kind has separate mosquito vectors and each kind has unique Protozoan Parasites.

Some kinds of serious virus diseases, such as many kinds of Encephalitis (or Encephalomyelitis) require an insect to pick up the virus from a host, amplify it, and then pass the virus on to whatever host it feeds on next. Many of the human and animal "encephalitis" diseases require susceptible vertebrate endemic or reservoir hosts to develop a viremia, and to have these viruses available to insects before that reservoir host animal develops antibodies to the virus, and thus becomes non-infective. Human or livestock disease can occur when an infected mosquito feeds on a person or other animal that is susceptible to the virus.

At one time, before the development of the vaccine, Poliomyelitis was thought to be mechanically transmitted by house flies. This did not involve a specific vector, but was thought to be mechanically carried by anything which would feed on body fluids from a sick host, and then carry the virus to a new host.

The kinds of encephalitis which the public has come to understand often goes by the name of the place where it was first found. For example, St. Louis Encephalitis (SLE) was first isolated from St Louis, but it is widespread over broad areas of North America. Just a few years ago, an epidemic of SLE occurred near Disney World in Florida, and caused widespread illness, death and fear sufficient to cause severe economic disruption of the tourist trade.

Other kinds of encephalitis which occasionally occur in the United States include Western Equine (severe in horses as well as people) Eastern Equine (also severe in horses as well as people), and LaCrosse encephalitis which is insidious by causing delayed neurological effects. There are other potentially serious insect vectored virus diseases, such as Japanese B Encephalitis, California

Encephalitis, Venezuelan Equine Encephalitis, Dengue and Dengue Hemorrhagic fever, and Yellow Fever. All of these are vectored by insects, primarily mosquitoes. Other similar, but as yet unidentified diseases are possible, because there are new virus antibodies being found which are not yet associated with human or animal diseases. Even mosquitoes found in snow-melt pools in mountainous areas of California have been found to carry viruses of unknown disease significance.

The usual cycle of many of these diseases of humans and other animals involves wild birds. These birds serve as the endemic or amplifying host, where the virus is either active all year round or possibly carried in by a migrating host, often another bird species. There are less common endemic cycles involving Jackrabbits, for example, but the most common cycle appears to be in local wild birds. Current evidence suggests that some of the migratory wetland birds, such as Herrons and similar bird species, are involved in longer distance transport and importation of the viruses, which may have died out after the last mosquito breeding season.

Wetlands are an obvious breeding place for mosquito vectors, and thus they have a high risk of diseases associated with them, whether they are new or old wetlands. Eastern Equine Encephalitis (EEE) transmission may involve two species of mosquitoes, one for the endemic cycle and another for the epidemic cycle in which humans, and horses can be infected. In the case of endangered birds, the cycle is direct, with the degree of mortality depending on the severity of the viremia produced and whether the host dies before it can recover and produce antibodies for immunity to later infections. Pheasant Farmers in the midwest have experienced severe epidemics in their pen reared birds from EEE virus.

Bird Malaria is apparently not a particular problem in Game species, which seem to occupy most of the Wildlife Biologist's attention.

Virus Diseases in Endangered Species:

The best example of severe disease and death of an Endangered Species caused by a mosquito vectored virus disease is in Whooping Cranes. The captive breeding program at the Federal Government's Pautextent Wildlife Refuge in Maryland is trying to produce enough of these birds to reintroduce them into the wild. In 1984, 7 of 23 birds died from EEE at the station, and 7 others had naturally produced antibodies. The remaining live birds were inoculated with an experimental vaccine. This apparently was successful, but any of the birds which are produced in the wild, even from vaccinated parent birds, will be susceptible to this virus. The introduction plan calls for putting these birds

into an area which is known for having EEE epidemic conditions in the past.

With the discovery of the extreme susceptibility of Whooping Cranes to EEE, a plausible explanation for the near extinction of these birds now exists. There are two major migration routes used by these birds in the past; one was from Canada to the Southeastern U.S., and the other was from Canada to Texas. The natural range for EEE as we know it is from the central Midwest to New England, south to the Southeastern U.S. This area seems to include a large part of the migration routes of these birds.

Sand Hill Cranes are a related species which is susceptible to EEE virus infection, but apparently, this species does not experience the extremely high mortality seen in Whooping Cranes. Even Bald Eagles held at the Pautextent Station have been infected and show antibodies to EEE.

It is obvious that Cranes in nature can not be easily captured and vaccinated, which leaves mosquito control as the best way to protect these scarce birds from EEE.

At the same time the Pautextent Station (in Maryland) was experiencing its epidemic and up to today, the National Park Service has refused to allow vaccination of the wild horses on Assateague Island in Eastern Maryland. EEE is a severe disease of unvaccinated horses, and results in a day or so of symptoms before the horses usually die. A sick horse lies on its side and tries to run, but only succeeds in digging an arched area where its hoofs scrape the ground. The reason given by the Park Service for not allowing mosquito control to protect these horses is the NPS' goal of getting rid of the horses on the island, so it can go back to its natural pre-human condition. The horses were introduced by man.

Another discovery about encephalitis was made, as a result of laboratory experiments on Kangaroo Rats, before the populations were listed as endangered. The University of California Virus Disease Research Station at Bakersfield, California used 2 species of local Kangaroo Rats as test animals. The research was aimed at finding the endemic and epidemic species of animals involved in transmission of the two virus strains which had been epidemic in California. The "Fresno" Kangaroo Rat was extremely susceptible to Western Equine Encephalomyelitis (WEE) and the "Heermann" Kangaroo Rat was also susceptible to the virus disease, but not quite as severely.

After this research was completed, there were 5 species of these Rats listed by the Federal Government as endangered. California lists 12 species or subspecies, 7 of which are subspecies of the two species tested earlier by

the University workers.

Sanctuaries which have been created for these rats include the Salt Bush type of habitat which the Rats like. The kind of land in the Southern San Joaquin where Salt Bush is found is not good agricultural land, and so Refuges have been established. These Refuges are often surrounded by Duck Hunting Clubs, which have created "wetlands" for ducks, but which at the same time have created ideal mosquito breeding habitat. These wetlands are also attractive areas for wild birds which could serve as transporters of the virus in addition to serving as the endemic hosts, to increase the amount of virus. With the high degree of susceptibility of these Kangaroo Rats to WEE, it is a wonder they have not been wiped out in these Refuges. In other parts of the Valley where the virus occurs periodically at epidemic levels, there is risk to these Rats as well, but at a possibly reduced level.

The University research on Human and other animal encephalitis diseases, and the viruses which can cause them, did not particularly consider wild animal survival. The disease research was directed toward human and horse cases, and disease suppression. The data on Rats and other animals was only salvaged from the information presented in the researcher's studies. A review of only two studies showed that antibodies were present for WEE or SLE in Tricolored Blackbirds, Harvest Mice, Antelope Ground Squirrels, and Cotton Rats, as well as in Kangaroo Rats. All of these species, or closely related species are on the Federal Endangered Species list, or the California List. The same paper which reported the Whooping Crane problems reported finding antibodies to EEE virus in Bald Eagles kept at the station in Maryland.

The Bluetongue virus in Big Horned Sheep is vectored by Culicoides Gnats, and this same disease is prevalent in Deer. Entire populations of these sheep have been exterminated by this disease, yet no effort has been made to vaccinate the sheep or to control the Gnat vectors. This lack of disease control has occurred, despite the tremendous costs of trying to reestablish colonizing Sheep populations. Building "exclusion fences" and protection from other adverse impacts has been practiced, while control of the vector has been ignored.

As far as I know, there is no active program to collect and test blood for virus antibodies from other bird or mammal species which are on the Endangered Species List, or are active candidates for listing. A prudent person should want to have this kind of data, because the Endangered Species Act mandates that all Agencies of the Federal Government are supposed to do everything possible to protect and even to increase all Endangered Species.

Mosquito Control Perspective:

The anti-pesticide movement and the wetland restoration promoters together have fostered an attitude in the Federal and State Governments which is a serious detriment to mosquito control. Not only do Humans suffer because of this attitude, but some Endangered Species are suffering from it as well. The Federal EPA has a strong bias against reregistration of any pesticide until a whole series of safety studies are completed and submitted to them for review. In the mean time, this Agency neglects its Legislatively imposed requirement which mandates a Risk/Benefit balancing. The present attitude of the Agency seems opposed to accepting a small insignificant risk, in order to allow the benefit of Human Health Protection. The Mandate to do everything necessary to protect the continued existence of Endangered Species, such as encouraging the registration of effective pesticides to control the mosquito vectors of virus diseases which can kill these Endangered Species is apparently completely overlooked as well.

Even the U.S.Department of Interior and its Fish and Wildlife Service have been leading opponents of mosquito control on their Refuges. They claim a concern for Endangered and Game species, as well as common wildlife, yet when these species may be directly effected by mosquito vectored diseases, or they may serve as endemic hosts for these virus diseases of people and wildlife, they adopt an attitude of indifference.

One Refuge Management Person said that flying adult insects were the food for a California listed bird on his refuge, and therefore anything that reduced the adult insects, such as chemical mosquito control on the Refuge would not be allowed under most conditions. This kind of attitude must change.

If the Endangered Species Act mandates protection of Endangered Species, then the Agencies of the Federal Government should join with Organized Mosquito Control to expedite reregistration of pesticides, and to work to remove the other roadblocks to the beneficial use of pesticides to protect Endangered Species.

The traditional beliefs that pesticides are detrimental to wildlife and are not "natural" are actually contributing to the loss of animals which have been declared as endangered. These anti-pesticide beliefs need to be replaced with an understanding of the positive benefits which pesticides can provide in protecting man's well being, as well as in protecting endangered species.

TESTIMONY OF DR. GEORGE TEMPLETON

Mr. Chairman,

I am honored to appear before your subcommittee to share my experiences in pesticide registration and re-registration processes for the federal government. I commend this subcommittee's efforts to develop policies leading to improved economic incentives and increased academic research for development and registration of effective biological alternatives for pest control.

It is obvious to all that greater reliance on biological alternatives for pest control is essential if we are to reduce production costs, control pests now resistant to chemicals and lessen public concerns for environmental quality, food safety and ground water contamination. Pest control in the 21st century must rely more heavily upon biologicals than in the past, and to achieve this will require united resolve of federal and state regulatory agencies, academic and industrial scientists, user groups and the public to formulate policy and procedures for registration based on sound science rather than perceived or imagined risk. The challenge of funding, researching, evaluating, developing and employing biologicals is already too daunting to endure the additional burden of extravagant, unreasonable and unscientific regulatory requirements. The country must have change to succeed in establishing biologicals as the major component of pest management in the near future.

_____ 1
Dr. George Templeton, University of Arkansas

RELEVANT BIOGRAPHY

My testimony is based on 24 years of experience in research, development, registration and commercial use of COLLEGO™, a bioherbicide for control of northern jointvetch weeds in Arkansas rice fields. I am a Distinguished Professor in the Department of Plant Pathology, College of Agriculture and Home Economics, University of Arkansas and a project leader in its Alternative Pest Control Research Center.

I have been a member of the Technical Committee of the Southern Regional Research Project on "Biological Control of Weeds with Plant Pathogens" since its inception and served as its first chairman. I am a Fellow of the American Phytopathological Society and was instrumental in establishing its biological control committee. I am also a member of the Mycological Society of America, the British Mycological Society, the Weed Science Society of America and the International Weed Science Society.

I have been active in establishment of the International Bioherbicide Group and currently serve as chairman of the steering committee for this new organization. I occasionally serve as a consultant to industry on bioherbicides, and I currently serve as the U.S. agent for a Canadian company seeking U.S. registration of a bioherbicide for a weed that represents a small market potential.

I have collaborated with scientists in Australia, Canada, Japan, South Africa, Switzerland, Holland, Italy, Thailand and England to initiate biological herbicide projects. I received the USDA Superior Service Award in 1990 "For pioneering research and collaboration with agencies and industry that established the commercial feasibility of using indigenous weed disease fungi as alternatives to chemical weed killers." The American Phytopathological Society recognized my effort with the Ruth Allen Award in 1991.

THE CURRENT SITUATION

The Environmental Protection Agency (EPA) regulations recognize that microbial pesticides pose lower risks to the public and environment than chemical pesticides due to their natural occurrence, low use rates, high specificity and lack of persistence. The top 20 chemical pesticide companies agree that the cost, time and regulation procedures for microbials are not much of

an issue. The large companies are mostly constrained by low-market potential of most microbials relative to their high overhead costs. Thus, they leave commercialization of highly specific, niche-market microbials to small, regional companies, most of whom do not have research or regulatory staff. The small companies accept technology from public sector research laboratories that likewise do not have competence or interest in registration procedures. Consequently, registration procedures as well as development costs become almost insurmountable barriers to entrepreneurs or managers of small businesses considering development of biological pesticides.

By themselves, regulations continue to be the major disincentive to commercial development of microbial pesticides by industry. For example, there are at least nine "orphan" bioherbicides that could be currently used if not for costs of registration. There are only two bioherbicides registered in the United States, COLLEGO™ and DEVINE™. After more than a decade of safe, effective use, the bioherbicide concept sadly remains more of a curiosity than an effective alternative to chemical herbicides. Again, this is due to the return on investment of these highly specific but safe products being too small in light of existing registration costs and requirements. The advantages of reduced risk to the public from using these products are nullified by the economic disadvantage of low-market potential resulting from high specificity.

INCENTIVES TO ENCOURAGE BIOHERBICIDE COMMERCIALIZATION

Several practical means can be used to reduce registration costs and accelerate the registration process for these safe, non-polluting natural pest controls, which will enhance their potential to reduce chemical pesticide risks and use. For example, significant parts of the development costs for these low-risk microbial pesticides are the fees and expenses of toxicology tests required for experimental use permits and applications for registration, including exemption from the requirement of a residue tolerance. These items cost \$250,000 or more per product. Although these figures are modest when compared to those for broad-spectrum chemical pesticides, they discourage the development of low risk biopesticides even when substantial waivers of fees and data requirements are approved. Registration costs for a group of

single-target biopesticides to replace one broad-spectrum chemical pesticide could possibly be greater than that for a particular chemical. Removing or reducing these costs would be an important incentive for development of safe, ecologically sound, microbial pesticides.

Additional incentives include deferral of fees until the product is well established, forgiveness of fees based upon amount of chemical pesticide replaced by the microbial, or a tax credit for development of "orphan" products, patterned after the orphan drug policy. Creative changes in regulations and policy by the EPA are needed to overcome the economic disincentive to commercialization of microbes by small businesses.

COST OF RE-REGISTRATION MAY REMOVE SAFE PRODUCT

A decade of experience with the bioherbicide COLLEGO™ illustrates the economic disincentive of current registration requirements to commercialization of highly specific, niche-market microbials. COLLEGO™ is used on approximately 10,000 acres of rice each year and only in Arkansas. Cost of development of the product over a 13-year period has been estimated to be \$2,000,000—a rough estimate because of the multiagency, multidisciplinary, public-private sector team involved in its development and the excessively cautious regulatory position of EPA concerning this first bioherbicide.

The wholesale price of COLLEGO™ is \$5.88 per acre, and cost of goods is \$2.36. Returns are therefore about \$35,200 per year from the 10,000 acres treated. At this price and use rate, it will take 56 years of sales to equal the cost of development of the product. Most chemical pesticides must return their development cost in 10 years or less to be considered marketable.

Environmental pollution is another important byproduct to be considered. COLLEGO™ could replace 2,500 gallons of 2,4,5-T annually if this chemical were still on the market. However, it would still compete poorly with 2,4,5-T because of costs and spectrum of weeds controlled by the chemical. COLLEGO™ survives today because it is highly effective, returning about four dollars to the grower for every dollar invested in application, and because there is no other control method for northern jointvetch. (The development and registration costs of COLLEGO™ were borne by the public sector and not the production company or rice growers.) The cost of re-registering COLLEGO™ may place it in jeopardy of being removed from the market. It is

not likely to be replaced by a chemical herbicide; chemical herbicides are being designed with specificity against only major weeds and not northern jointvetch.

RATIONAL REGISTRATION POLICY WOULD BE AN INCENTIVE TO COMMERCIALIZATION

Another aspect to be considered is that the widespread use of broad-spectrum chemical herbicides over many years has led to selection of resistant weed populations. These populations are area-specific problems and represent niche markets of little interest to the chemical herbicide industry for economic reasons. The problem weeds would be ideal targets for highly specific microbial pathogens; however, encouragement from the EPA and other regulatory agencies is needed to induce small businesses to develop low-risk bioherbicides. A clear policy identifying microbial pathogens of weed plants, especially noxious weeds, as low risk and establishing appropriate and rational criteria for registration would be an important incentive to commercialization.

SAFETY OF BIOHERBICIDES

Total reorganization of the requirements for registration of microbials for weed control is justified in many cases. For example, there is extensive scientific evidence—about two centuries of experience with plant pathogenic microorganisms in general and two decades of research and experience with the COLLEGO™ fungus in particular—that affirms the safety to humans and the environment of indigenous plant pathogenic microbes when used as bioherbicides. It is an axiom of plant pathology that, with few debatable exceptions (unverified reports), fungal plant pathogens infect members of the plant kingdom not the animal kingdom. Therefore, the tiers of currently required toxicology tests with plant pathogens are largely irrelevant and could be omitted entirely without compromising human safety. The number of plant-associated microorganisms, including viruses, that pose a toxicant or highly allergenic safety concern to either humans or animals is less than a handful among the greater than 100,000 species thus far described.

More specifically, nontarget plants are the only relevant concern among the existing tiers of nontarget organism test requirements for potential bioherbicides. The other test requirements, i.e., avian oral, wild mammals, freshwater fish, aquatic invertebrate, estuarial and marine animals, nontarget insects and honeybee challenges, are a waste of effort, time and money and could be omitted without compromising environmental safety. The effort expended on these tests would be more productive if spent on tests more meaningful to the question of safety.

A MORE RATIONAL REGISTRATION PROCESS

A scientifically sound approach to the registration process would be to redirect efforts from toxicology and nontarget organism tests to research on the basic understanding of the disease etiology of the microorganisms being considered for use as a bioherbicide. Professional standards in plant pathology require a reasonable understanding of disease etiology before field tests are conducted with plant pathogens. Although it is not always possible to completely answer all questions about a disease etiology, reasonable inferences can be achieved from a combination of information in the literature on related diseases together with information gained by inoculation experiments under controlled environments. Major questions to be addressed include the following: Does the microorganism exhibit genetically stable host specificity? How is it dispersed? Does it persist from season to season, and if so, how? What are the biotic and abiotic constraints to its viability and dispersal? These data, together with knowledge of the microorganism's existing distribution in nature and intended use patterns can be used as a logical basis for host range test requirements of potential bioherbicides. In reality, they is nothing more that would be required to satisfy the professional standards of plant pathologists. A testing system embodying these principles would do much to encourage research and development of low-risk bioherbicides here and abroad. It is my view that EPA, FDA and USDA-APHIS could exempt indigenous weed pathogens to be used as bioherbicides from regulation without risks to the public or the environment.

PROFESSIONAL STANDARDS ASSURE SAFETY

In the case of COLLEGO™, professional standards were used over a four-year period, including peer review by three eminent plant pathologists, to affirm the safety of COLLEGO™ before the nine-year odyssey began with EPA to satisfy "safety" in a regulatory context. The professional standards were as follows:

1. Identification of the pathogen.
2. Search of literature on related pathogens and disease cycles.
3. Proposal of disease cycle from literature and experiments including cardinal temperature, means of overwintering and dissemination.
4. Verifying host specificity and genetic stability.
5. Determination of natural distribution and epidemiology.
6. Determination of behavior in field plots.
7. Publication.
8. Peer review by eminent pathologists.
9. Notification of state regulatory authority.
10. Issuing local and national publicity.

EPA REQUIREMENTS TO SATISFY SAFETY

PRODUCT ANALYSIS

- | | |
|------------------------------|-------------------------------------|
| 1. Product identity | 5. Certification of limits |
| 2. Manufacturing process | 6. Analytical methods |
| 3. Unintentional ingredients | 7. Physical and chemical properties |
| 4. Analysis of samples | 8. Submittal of sample |

TOXICOLOGY

- | | |
|------------------------------------|--|
| 1. Acute oral (3) | 6. Primary eye |
| 2. Acute dermal | 7. Hypersensitivity study ¹ |
| 3. Acute pulmonary (2) | 8. Hypersensitivity incidents |
| 4. Subacute pulmonary ¹ | 9. Cellular immune response ¹ |
| 5. Primary dermal (3) | 10. Interperitoneal injection ¹ |

¹ This procedure is not currently required by the Environmental Protection Agency.

NONTARGET ORGANISM — FATE AND EXPRESSION

- | | |
|--------------------|-----------------------------|
| 1. Avian oral (2) | 3. Freshwater fish |
| 2. Avian injection | 4. Freshwater invertebrates |

RESIDUE DATA²

- | | |
|---------------------------------------|---|
| 1. Spore Germination Temperature | 7. Bioassay of Irrigation Water |
| 2. Spore Thermal Death Point | 8. Bioassay of Soil |
| 3. Spore Shelf-life (dry) | 9. Mycoflora of Grain |
| 4. Spore Germ./Chem. Herbicides | 10. Bacterial Flora of Grain |
| 5. Aerobiology during Application (4) | 11. Fate of C14 Labeled Spore in Microecosystem |
| 6. Overwintering in Soil | 12. Overwintering in Weed Residue |

None of the EPA requirements conflicted with or significantly contributed to those tests used to satisfy professional standards of safety. The EPA requirements caused nearly a decade's delay in the use of COLLEGO™, resulting in the continued use of approximately 25,000 gallons of chemical pesticide. One of these chemicals was 2,4,5-T, which has been removed from the market due to its environmental and human hazard potential.

RECOMMENDATIONS

My recommendation is to require that only professional standards be met in development of microbes for weed control. Agency notification with a peer review system should be required. The peer review would be conducted either locally or nationally, similarly to how peers are used to review publications and grant proposals. Such a system would encourage researchers seeking biological alternatives to chemicals and would do so without creating unreasonable risk to the public or environment from these inherently safe, ecologically sound, environmentally neutral pest control agents. Ironically, it is easier to move a human pathogen in this country than it is to move an indigenous weed pathogen (Figs. 1a,1b.)

² No longer required if toxicology tests are negative.

Another recommendation would be to change label requirements to those more appropriate for biologicals, i.e. "user friendly" labels rather than warning labels. The current COLLEGO™ label (Fig. 2) for the spore rehydrating component, which is a corn syrup equivalent to Karo® Corn Syrup, has in large letters the following warning:

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

See side panel for precautionary statements.

On the side panels are storage and disposal instructions such as those used for high-risk chemical pesticides.

Similar, unnecessary warnings are on the label of the component containing the host specific microbe (Fig. 2b). These warnings cast unnecessary doubts as to the inherent safety of this new weed control technology, and researchers may come to doubt the scientific credibility of the regulatory system. It is imperative to make improvements in the system before microbial control can play a major part in pest management.

Summary

1. Bioherbicide alternatives for crop production are minimal.
2. Current acreage of crops treated in the United States with bioherbicides is trivial in comparison to traditional weed control materials.
3. Bioherbicides are highly beneficial because they are safe, specific for a single weed species, environmentally neutral and do not contaminate surface or ground water.
4. Bioherbicides are not attractive to traditional agrichemical companies because they represent only niche market potential.
5. Public/private sector technology transfer is essential to commercialization of bioherbicides by small companies.
6. Relaxation of registration and other regulatory requirements would provide critically needed encouragement for bioherbicide development.

7. Professional standards for research with plant pathogens could be substituted for current EPA, FDA and USDA regulations.
 8. A cooperative, rather than an adversarial, regulatory climate would improve chances for greater development of biological alternatives and help create a realistic public understanding of their safety and potential.
-

(Attachments follow:)

PERMITS AND FORMS

**Acceptance of Responsibility of Potentially
Highly Pathogenic (Class III) Materials**

I recognize that the material I have requested from the American Type Culture Collection represents a potential hazard to the public health and/or agriculture of the country. I am an investigator qualified through education and training to work with such material. I hereby assume all risk and responsibility in connection with the receipt, handling, storage and use of the material.

Institution

Department

Street Address

City

State/Zip

Country

Telephone

Telefax

Type or Print Name of Investigator

Signature of Investigator

Date

IMPORTANT — You have been assigned Account # _____

Please refer to this number on all future orders and inquiries.

American Type Culture Collection
12301 Parklawn Drive
Rockville, MD 20852

Figure 1A. Permit required to move human pathogens interstate.

PERMITS AND FORMS

No permit can be issued to move live plant pests or noxious weeds until an application is received (7 CFR 330 (live plant pests) or 7 CFR 360 (noxious weeds)).

See reverse side for additional information.

USAM APPROVED
OMB NO. 0579-0054

U.S. DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
PLANT PROTECTION AND QUARANTINE
BIOLOGICAL ASSESSMENT AND TAXONOMIC SUPPORT
HYATTSVILLE, MARYLAND 20782

SECTION A - TO BE COMPLETED BY THE APPLICANT

APPLICATION AND PERMIT TO MOVE
LIVE PLANT PESTS AND NOXIOUS WEEDS

3. TYPE OF PEST TO BE MOVED

- ☐ Arthropods ☐ Noxious Weeds
☐ Pathogens ☐ Other (Specify)

1. NAME, TITLE, AND ADDRESS (include Zip Code)

2. TELEPHONE NO.

A. SCIENTIFIC NAMES OF PESTS TO BE MOVED	B. CLASSIFICATION (Orders, Families, Races, or Strains)	C. LIFE STAGES IF APPLICABLE	D. NUMBER OF SPECIMENS OR UNITS	E. SHIPPED FROM (Country or State)	F. ARE PESTS ESTABLISHED IN U.S.	G. MAJOR HOST(S) OF THE PEST
4						
5						
6						

7. WHAT HOST MATERIALS WILL ACCOMPANY WHICH PESTS (indicate by line number)

8. DESTINATION	9. PORT OF ARRIVAL	10. APPROXIMATE DATE OF ARRIVAL OR INTERSTATE MOVEMENT
11. NO. OF SHIPMENTS	12. SUPPLIER	13. METHOD OF SHIPMENT <input type="checkbox"/> Air Mail <input type="checkbox"/> Air Freight <input type="checkbox"/> Baggage <input type="checkbox"/> Auto

14. INTENDED USE (Be specific; attach outline or intended research)

15. METHODS TO BE USED TO PREVENT PLANT PEST ESCAPE	16. METHOD OF FINAL DISPOSITION
17. Applicant must be a resident of the U.S.A. I/We agree to comply with the safeguards printed on the reverse of this form and understand that a permit may be subject to other conditions specified in Sections B and C.	SIGNATURE OF APPLICANT (Must be person named in Item 1)
	18. DATE

SECTION B - TO BE COMPLETED BY STATE OFFICIAL

19. RECOMMENDATION <input type="checkbox"/> Approve <input type="checkbox"/> Disapprove <input type="checkbox"/> Accept USDA Decision	20. CONDITIONS RECOMMENDED
21. SIGNATURE	22. TITLE
	STATE
	23. DATE

SECTION C - TO BE COMPLETED BY FEDERAL OFFICIAL

PERMIT

24. PERMIT NO.

(Permit not valid unless signed by an authorized official of the Animal and Plant Health Inspection Service)

Under authority of the Federal Plant Pest Act of May 23, 1957 or the Federal Noxious Weed Act of 1974, permission is hereby granted to the applicant named above to move the pests described, except as deleted, subject to the conditions stated on, or attached to this application. (See standard conditions on reverse side).

This permit does not authorize the introduction, importation, interstate movement, or release into the environment of any genetically engineered organisms or products.

25. SIGNATURE OF PLANT PROTECTION AND QUARANTINE OFFICIAL	26. DATE	27. LABELS ISSUED	28. VALID UNTIL	29. PEST CATEGORY
---	----------	-------------------	-----------------	-------------------

PPQ FORM 526 Previous editions may be used
(OCT 88)

Figure 1B. Permit to move weed pathogen interstate (Current delay is more than eight months).



9-3249-2

Collego™

Component A
FUNGAL SPORE REHYDRATING AGENT

KEEP OUT OF REACH OF CHILDREN

CAUTION

See side panel for
precautionary statements

EPA Est. No. 1023-MI-2
NET VOLUME 1 QUART

USE BEFORE OCT. 1985
LOT 999 KF

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

See Booklet for complete directions for use.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

STORAGE: Store Collego Component A at temperatures of 40 to 60 °F.

PESTICIDE DISPOSAL: Pesticide spray mixture or rinsate that cannot be used according to label instructions must be disposed of according to Federal, State or local procedures under the Resource Conservation and Recovery Act.

CONTAINER DISPOSAL: Triple rinse (or equivalent) and offer for recycling or reconditioning, or dispose of in a sanitary landfill by incineration if permitted by state or local authorities.

812 233 000



Division of The Upjohn Company
Kalamazoo, Michigan 49001 U.S.A.

Figure 2A. Label and warning for corn syrup used as rehydrating agent for bioherbicide.

SPECIMEN LABEL

Collego®

SELECTIVE POSTEMERGENT HERBICIDE BIOLOGICAL WEED CONTROL AGENT

For Control of Northern Jointvetch (Curly Indigo) in Rice and Soybean

COLLEGO is a two component product.

COMPONENT A:

A fungal spore rehydrating agent.

COMPONENT B:

ACTIVE INGREDIENT

Colletotrichum gloeosporioides f. sp.
aeschynomene ATCC 20358

INERT INGREDIENTS

	15% *
	85%
Total	100%

* Contains at least 75.7×10^6 viable fungal spores.

EPA Reg. No. 45639-134-55638

PRECAUCION AL USUARIO: Si usted no lee ingles, no use este producto hasta que el etiqueta haya sido explicado ampliamente.

KEEP OUT OF REACH OF CHILDREN

CAUTION - PRECAUCION

STATEMENT OF PRACTICAL TREATMENT

IF IN EYES: RUSH WITH PLENTY OF WATER. GET MEDICAL ATTENTION IF IRRITATION PERSISTS. WASH THOROUGHLY WITH SOAP AND WATER AFTER HANDLING.

SEE SIDE PANELS FOR ADDITIONAL PRECAUTIONARY STATEMENTS

FIGURE

Figure 2B. Label and warnings required for microbial component of a bioherbicide.

NET CONTENTS

PRECAUTIONARY STATEMENTS

HAZARD TO HUMANS AND DOMESTIC ANIMALS

CAUTION

Causes slight eye irritation. Avoid contact with eyes or clothing.

ENVIRONMENTAL HAZARDS: Do not apply directly to water except as indicated in the directions for use. Do not contaminate water by cleaning of equipment or disposal of wastes.

SPECIFIC PRECAUTIONS

After 7 days following application, the grower should frequently examine the northern jointvetch (curly indigo) plants to determine if disease lesions are developing.

As with other pesticides, effectiveness of Collego may be reduced by mistakes in application, fertilization, cultivation and management practices. Results will be affected by extremes in weather, soil moisture, and temperature.

If the disease lesions caused by Collego do not reach one-half (1/2) inch in diameter and do not encircle the stems of the northern jointvetch (curly indigo) plants within 14 days after treatment, a second application of Collego should be made. See Application Rate and Recommendations Sections for Collego amounts and timing.

STORAGE AND DISPOSAL

Do not contaminate water, feed, or food by storage or disposal.

STORAGE: Store in original container and keep closed. Store Collego at temperatures of 40°F to 80°F. Collego contains viable fungal spores. Germination of these spores will be reduced by temperatures below 32°F or when Collego is held for 12 hours or more at temperatures above 105°F. Store in original container and keep closed.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

COMPONENT B BAG:

Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

GENERAL INFORMATION: Collego is a selective postemergent mycoherbicide which is a specific biological weed control agent. Postemergent applications of Collego will selectively control NORTHERN JOINTVETCH (curly indigo) *Aeschynomene virginica* (L.) B.S.P. in rice (*Oryza sativa* L.) and soybean (*Glycine max* (L.) Merr.) To prevent seed production, Collego should be applied when northern jointvetch plants are 12 OR MORE INCHES TALL AND HAVE NOT REACHED THE BLOOM STAGE. Collego will cause disease lesions that will completely encircle the stems of the northern jointvetch plants. The fungus primarily infects the stems of the weed but it also infects the petioles and leaflets.

Disease plants become limp; they may collapse. Plants not killed by Collego are stunted, unthrifty, unable to compete with the rice or soybean and will not be able to seed. Death of northern jointvetch plants may not occur for five (5) weeks after application.

Collego is a two component product. Collego Component A consists of three 1-quart bottles containing a water soluble spore rehydrating agent that allows the spores to take up water prior to germination. Collego Component B consists of three bags that contain a water suspendible dried fungal spore formulation of *Colletotrichum gloeosporioides* f.sp. *aeschynomene* ATCC 20358. Both components are packaged in a 5 gallon plastic mixing container with a lid and stirring paddle.

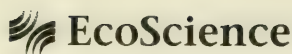
APPLICATION RATE: Collego Component A (1 quart) and Component B (1 bag) will treat 10 acres.

ACREAGE TO BE TREATED	AMOUNT REQUIRED	
	COMPONENT A	COMPONENT B
10	1 quart	1 bag
20	2 quarts	2 bags
30	3 quarts	3 bags

RECOMMENDATIONS FOR CONTROL OF NORTHERN JOINTVETCH (CURLY INDIGO)

CROP	WHEN TO APPLY COLLEGO	REMARKS
RICE	At any vegetative stage of rice growth if the northern jointvetch is at least 12 inches tall. Rice fields should be flooded before application.	To prevent northern jointvetch from setting seed. Collego must be applied prior to bloom. Application of Collego to northern jointvetch in bloom or postbloom will not completely prevent seed development. Northern jointvetch usually begins to bloom at about the same time as rice heads are emerging from the boot or pods are forming on the lower nodes of soybean plants.
SOYBEAN	After the soybean plants begin to flower; if the northern jointvetch is at least 12 inches tall. Soybean fields should be irrigated just prior to application.	

* Collego is exempt from the requirement of a tolerance for residues in or on rice and soybean when used according to these directions for use.



WRITTEN SUBMISSION OF JAMES A. WYLIE, JR.
PRESIDENT AND CHIEF EXECUTIVE OFFICER
ECOSCIENCE CORPORATION
BEFORE THE SUBCOMMITTEE ON
DEPARTMENT OPERATIONS AND NUTRITION
COMMITTEE ON AGRICULTURE
JUNE 10, 1993

Good morning, Chairman Stenholm, Vice Chairman Brown, Members of the Subcommittee on Department Operations and Nutrition and other interested parties.

My name is James A. Wylie. I am President and CEO of EcoScience Corporation. EcoScience is an emerging growth company focused on developing and commercializing safe and cost effective natural pest control products (biopesticides) as alternatives to conventional chemical pesticides. EcoScience biopesticides have several distinct advantages over chemical pesticides. They are naturally occurring microorganisms; they are not genetically modified. They are derived from the environment and are compatible with the environment. These agents can be safely used against a wide range of pests including insects, weeds and diseases of plants, fruits and vegetables. Effectively formulated, stabilized and delivered, these biopesticides are not only successful at controlling pest populations, they are simple to use and cost effective.

EcoScience Corporation

One Innovation Drive Worcester, MA 01605 (508) 754-0300 FAX (508) 754-1134

Our Company, originally financed with venture capital, has grown from a staff of 4 in 1988 to 131 employees today. This significant staff growth was required to effectively move products from research through field development, registration and into new product commercialization. During this early growth, EcoScience rapidly outpaced its ability to access sufficient private funding to support and sustain the intensive research and development programs required in our highly competitive industry. Accordingly, in early 1992 EcoScience successfully completed an Initial Public Offering of Common Stock. As a publicly traded company, we now have the potential to raise the capital necessary to bring innovative products to market.

Although the large multinational pesticide companies are aggressively pursuing new generations of safer chemical pesticides for large agricultural markets, they are not focused on the development and commercialization of naturally occurring microbial pest control agents. Chemical product development is still, by far, the biggest money maker for the large pesticide companies. While EcoScience and the handful of similar biopesticide companies offer the best hope in the near term for development and commercialization of environmentally compatible products, these companies are being increasingly frustrated by the governmental regulatory regime that determines the ultimate fate of our products. In short, there is a conflict between the viability of our industry segment and EPA's regulatory review process. Without a healthy, well-financed and effectively regulated biopesticide industry, the American public will not have near-term access to the safer, more environmentally

compatible products that they are demanding. Equally important, the United States could lose its technical leadership to foreign competition.

As Chief Executive of one of the small public companies in the field of biopesticides, I am growing increasingly concerned that the future of our industry segment could be in serious jeopardy. Attracting and, most importantly, keeping investor support is critical to the viability of our industry. Today, firms like EcoScience rely heavily on the public markets to provide necessary funding to support basic research, new product commercialization and capital investment in production facilities. Government regulatory time frames create uncertainty and severely impact our ability to attract the additional capital necessary to develop new and safer biopesticides products. This uncertainty is so great that large numbers of potential investors are afraid to invest in our growth industry.

My purpose for being here today is not to criticize the EPA, which has dedicated personnel, doing an enormous job, under very difficult constraints; but rather to make you aware of the issues facing this industry's emerging new businesses. Our goal is that together the biopesticide industry and EPA can seek, develop and implement solutions to enhance the regulatory process while, at the same time, improving public health and environmental quality.

Some time ago, EPA recognized that biological pesticides posed far fewer risks to human health and the environment than chemical-based

pesticides. In fact, in many cases standard testing requirements for chemical pesticides were not appropriate for these new products. In recognition of this difference, EPA designed and published Subdivision M Data Guidelines for biorational pesticides. Unfortunately, while these guidelines provide an acceptable procedural framework to accelerate registration, EPA has not been able to effectively implement this policy. Consequently, although testing requirements for microbial agents are significantly less than those for chemical pesticides, actual product review times remain excessively long and, worse, unpredictable.

Unless a way can be found to accelerate and predict the registration timeframe, companies like ours will find it increasingly difficult to access the public markets for financing. Investors look for, and appropriately demand, return on their investments. Today, it is impossible to reliably learn the status of applications and to project with any accuracy the timing of a new product registration. The lengthy and unpredictable regulatory review process for new microbial-based biopesticide products can cause investors to become disillusioned and seek alternative investments in non-regulated industries. Without the availability of equity funding, companies like EcoScience will disappear, microbial-based biological pesticide research will be severely hampered and innovation stifled.

The President's recently announced initiative, "Technology for America's Economic Growth, A New Direction to Build Economic Strength," cited our type of problem for review and specifically referred to improving the regulatory climate for environmentally compatible products. Perhaps EPA

could implement this Presidential initiative by elevating microbial pesticide review and registration to a high priority within the department. With Subdivision M already in place, it would seem that all that is necessary is commitment and leadership. We are eager to work with the new EPA Administrator to develop a strategy that would make a biopesticide registration policy a concrete example of the President's technology initiative. Companies like EcoScience appear to fit every criteria for such a national policy -- an emerging industry that is rapidly creating high-paying, scientifically based job opportunities while developing and commercializing environmentally compatible products.

EPA has identified the field of microbial agents as a potential source of pest control products that can be safer to humans and the environment. In addition, EPA recognized the inherent safety of microbials when it established the Subdivision M process and went further to provide that microbial product registration should occur in one year.

Developing pesticides for sale and securing EPA registrations is a costly, complex and intensively demanding process. However, a typical microbial agent registration package is relatively quite small compared to the volumes of data filed on chemical products. Therefore, the time required for microbial review should be shorter. Despite the one year guideline and fewer and less complex studies that are required, it is not unusual for the registration process for microbial products to take as much as two years or more to complete. Unfortunately, product reviews have been consistently delayed because certain scientific review

branches within the Office of Pesticide Programs (OPP) have to manage both chemical and biological products. Since the data packages for chemical products are far more extensive and often contain a range of technical issues to contend with, reviewers must spend more time on these data packages thus severely slowing down the review process for biopesticide products. Unless an issue is uncovered in testing, review of the typical biopesticide package could be completed in a matter of weeks, not years.

EPA has spent considerable time over the last two years considering measures to improve the registration process for "reduced risk" pesticides. In January EPA published an update on the Office of Pesticide Programs initiative to establish incentives for the registration of "reduced risk" pesticides (58 Federal Register 5854). EPA is continuing to develop criteria for defining "reduced risk" pesticides and possible incentives to intensify research in the area. However, our Company believes that the extensive regulatory framework is in place to provide acceleration of biological product registration.

In addition to the issues of registration timeframe and predictability, we have one other deep concern. This concern is related to the Agency's overly restrictive position on the labeling claims of some biological pesticides. As an example, EcoScience products are derived from nature without being altered. In fact, the organisms which serve as our active ingredients are found everywhere in nature. Today, firms like EcoScience are prohibited from stating that our products are "natural" or "naturally

occurring" organisms. We are not even permitted to state that the product contains "no chemical pesticide." The Agency's position is that, notwithstanding the literal truth of the product's composition, these words imply safety claims -- we disagree.

Mr. Chairman, the public has the right to know that a product is made from naturally occurring substances. They certainly should have the right to know that a product contains no chemicals. The consumer should have the right to make their decision on what product to select based on full disclosure, not just the essentially meaningless inclusion of an organism's name (i.e. *Metarhizium anisopliae*). EPA's current position is actually a deterrent to stimulating consumer demand for more environmentally compatible, safer alternatives to conventional chemical pesticides. The prohibition of these words removes the competitive distinction of our products and leads to an uninformed public. What is the purpose of making these products if the public can have no meaningful way to compare?

In summary, Mr. Chairman, the overall effect of these regulatory delays is that product commercialization is delayed, investors lose interest, research money dries up and environmentally compatible products are not made available to the public. I believe that most of these problems can be alleviated by a strong policy imposed by EPA leadership to place a high priority on environmentally compatible products and strictly enforce the policy through a dedicated management commitment.

As part of this policy, EcoScience recommends the following steps for consideration.

1. First and foremost, Mr. Chairman, urge the EPA leadership to place a high priority on biopesticide registration by establishing a strong policy to implement Subdivision M.
2. EPA should create a separate branch within OPP to implement and manage the registration of microbial, biochemical and plant pesticide products under Subdivision M.
3. The proposed branch should be staffed with a dedicated team of scientifically knowledgeable reviewers focused solely on biopesticide product registration.
4. Biological pesticides should be excluded from the "reduced risk" pesticide policy currently under development at EPA to ensure focused review and accelerated registration.
5. Data review and product registration should be accomplished within six months. Most importantly, if there are no valid technical issues with the data package, final registration time frames must be met and be predictable.
6. Naturally occurring, non-genetically modified biopesticide registrations should be allowed to make the following label claims:

- "Natural" or "Naturally Occurring"
- "Contains No Chemical Pesticide"

EcoScience stands ready to work closely with EPA and your Committee to seek effective solutions to the complex problems of pesticide registration.

Thank you for the opportunity to express our views.

STATEMENT OF
DR. JAMES H. DAVIS, VICE PRESIDENT
CROP GENETICS INTERNATIONAL CORP.
ON BEHALF OF THE
INDUSTRIAL BIOTECHNOLOGY ASSOCIATION
BEFORE THE
SUBCOMMITTEE ON DEPARTMENT OPERATIONS
AND NUTRITION
OF THE
HOUSE COMMITTEE ON AGRICULTURE

JUNE 10, 1993

Mr. Chairman and members of the subcommittee, I am Jim Davis, Vice President for Research and Development and General Counsel at Crop Genetics International. Crop Genetics is engaged in the development of new approaches to biological pest control including the use of both genetically-engineered and naturally-occurring microorganisms. I am here today representing the member companies of the Industrial Biotechnology Association (IBA). On behalf of the Association, I would like to thank you and other subcommittee members for inviting us to present our perspective on current pesticide registration issues.

IBA currently is completing plans to merge with the Association of Biotechnology Companies. This merger will be completed July 1. Afterwards the new organizations will operate as the Biotechnology Industry Organization (BIO).

IBA represents 157 large and small companies engaged in all forms of biotechnology R&D and manufacturing including the major manufacturers of biological pesticides. Collectively, IBA member companies account for greater than 90% of the sales of microbial pesticides in the United States. Member companies are actively developing new biological solutions to crop protection, including the use of genetically modified crop plants with improved insect and disease resistance. Many of these products are likely to be subject to EPA regulation under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

IBA's member companies include dedicated biotechnology companies formed within the last fifteen years as well as large multinational companies with substantive interests in

biotechnology. All share a commitment to developing improved environmentally-friendly approaches to pest control.

Seventeen new microbial active ingredients have been registered by EPA since 1988. These new products account for over one half the currently registered microbials. Last December EPA presented a draft proposal for the regulation of transgenic plant pesticides. IBA anticipates that biological products such as transgenic plants and microbial pesticides will account for more than half of the new active ingredients submitted to EPA for registration over the next several years. These biological approaches to pest control are expected to play an increasing role in Integrated Pest Management (IPM) schemes, and in improving the environmental safety of American agriculture.

My testimony today will focus on an organizational approach for improving the registration of biological pest control agents as well as the recent EPA initiative on reduced risk pesticides. IBA and its member companies believe that research into biological products is not only a laudable goal but a necessary one for insuring the competitiveness of American agriculture. Prompt registration of reduced risk pesticides is essential for insuring the success of these products. Improving registration procedures for these products will expand the choice of new pest control approaches for farmers, nurserymen, and foresters throughout the country.

This past January EPA published an update on the Office of Pesticide Programs (OPP) initiative to establish incentives for the registration of reduced risk pesticides (58 Federal Register 5854). EPA is continuing to develop criteria for defining "reduced risk" pesticides as well as the types of incentives that could be employed to improve research and developments of such products. While deliberations on definitions may be useful for chemical pesticides, an appropriate registration pathway for biologicals already exists.

Over ten years ago, EPA recognized that biological pesticides posed far fewer risks to human health and the environment. Traditional data requirements for chemical pesticides were in many cases not applicable to biologicals. The EPA technical staff designed the Subdivision M Data Guidelines for biorational pesticides in recognition of this fact. Under Subdivision M, the data required to support the registration of biological pesticides are significantly less than that required for chemically-derived pesticides. The Guidelines include a three tier approach to hazard assessment. Products that successfully pass the Tier One tests can be registered without further more costly Tier Two or Tier Three testing. No registered biological pesticide has required any testing beyond Tier One. Clearly the biological products fit any definition of "reduced risk" pesticides.

The central issue facing EPA and industry is how to expedite the data review and registration of these "reduced-risk" biological products. IBA believes that registration product reviews should be completed within six months of data submission. EPA has taken several steps over the past several years to facilitate the registration process for biologicals.

Two product review teams have been dedicated to the review and registration of these products. Unfortunately, product reviews have been delayed in the past because certain scientific review branches within OPP deal with both chemical and biological products. Since the data packages for chemical products are more complex, reviewers must spend more time on these products thus slowing down the review process for other products in the queue. Moreover, many reviewers are often sidetracked into reregistration issues significantly delaying their review of new and reduced risk pesticides.

EPA's commitment to registering "reduced-risk" pesticides must include both a reexamination of management practices as well as the commitment of adequate resources to the product review process. IBA believes that this can best be accomplished by the establishment of a separate branch within OPP's Registration Division to handle the review of biological products. With a dedicated team of reviewers whose primary responsibility is the review of registration data for these reduced risk products, EPA will be able to facilitate markedly the registration process and handle the increasing number of biological submissions. EPA already has sufficient expertise within OPP to staff such a division.

A separate branch, as described above, would permit OPP to make quick decisions on testing protocols. New protocols are handled on a case-by-case basis. Prompt decisions on the validity of the protocol are required to facilitate the testing process needed to acquire the necessary data supporting product registration.

IBA believes that the single most important step EPA could take toward encouraging reduced risk pesticides is to implement management changes, such as the one proposed above, that would speed up the registration process for biological approaches to pest control. With the establishment of the biologicals branch and a commitment to prompt review, we strongly believe that products can and should be reviewed and registered in six months. We have communicated our views to EPA and plan to meet with the agency shortly to discuss the implementation of our proposed changes.

STATEMENT OF
DR. JERRY CAULDER, PRESIDENT AND CEO
MYCOGEN CORPORATION
ON THE REGISTRATION OF ALTERNATIVE PEST CONTROL AGENTS

Let me begin by thanking you, Mr. Chairman, Congressman Smith, and all the members of the Subcommittee for inviting me to testify on EPA's registration process for alternative pest control agents. I am Dr. Jerry Caulder, President and CEO of Mycogen Corporation, a diversified agricultural biotechnology company. We develop and market environmentally compatible, effective biopesticides to control pests. We also improve crop varieties to increase food production. Since Mycogen was the first company to receive EPA approval for a genetically engineered biological pesticide, I will describe our experience with EPA's registration process. As background, the registered Mycogen product contains a naturally-occurring pest toxin from the *Bacillus thuringiensis* (Bt) bacterium. The toxin is inserted into another kind of bacteria which is then killed, stabilizing the toxin within its cell wall. Farmers find the encapsulated active ingredient lasts twice as long as traditional Bt in the field.

Mycogen has several EPA approved products; however, we are not the only ones. Many other biotech and chemical companies have invested heavily in research to find alternative pest control agents. Biological approaches to pest control, including the use of microbial pesticides and transgenic plants, are expected to play an increasing role in Integrated Pest Management (IPM) strategies. Improving registration procedures for these agents will expand the choice of new pest control approaches for farmers, nurserymen, foresters, and even avid weekend horticulturists nationwide.

To understand the registration process and my recommended changes, I will briefly discuss alternative pesticides in a broader context. I own a farm in Missouri and began my career developing and marketing chemically-based pesticides. At the time, these crop protection agents were perceived as radical tools that would revolutionize agriculture. Agricultural practices have changed and, consequently, the American farmer is viewed as the most

productive and efficient farmer in the world. But, some chemical pesticides have already lost their effectiveness as insects have developed resistance to them, and the list is growing. Others have left residues in food and ground water which have raised public concern.

Although chemical pesticides will be needed well into the next century, both traditional chemical companies and biotech firms are committed to finding alternatives to replace noxious products and to safely and effectively control chemical-resistant pests. A wide array of new products have been developed. Many have been tested in the fields. Most are stalled at EPA awaiting registration. The prolonged delay before commercialization troubles growers and investors alike. While companies await EPA's approval, farmers, and consequently the public, are denied an array of effective alternatives.

Let's take Mycogen as an example. Mycogen began research eight years ago to develop an effective biopesticide for control of the diamondback moth on vegetable crops because this pest had developed resistance to all synthetic chemical pesticides. Despite the fact that the toxin in MVP is highly-specific to moths and has no effect on beneficial insects, mammals, birds, fish, or the environment, it took EPA two years to grant Mycogen approval for commercial sale of MVP. Prior to approval, EPA took an unprecedented 16 months to grant an Experimental Use Permit (EUP) to field test MVP Bioinsecticide, even though we submitted all data necessary for full product registration. In early 1991, with final approval pending, EPA decided that the application would be singled out for review by another Office within the agency. That review kept us out of the market for the 1991 season. This decision to have a dual review was both duplicative and inefficient. Mycogen complied totally with all requests for data and resubmitted duplicates of reports lost by the agency. In return, we had expected effective, efficient, and timely review of our application. EPA's registration process dragged on, turned in circles, and ultimately failed to provide timely registration.

What barriers can be removed to make the regulatory process more responsive and efficient for alternative pest control agents? To ensure that reduced risk pesticides become available to the farmer without undue delay and that they are used widely and appropriately by farmers, EPA's Office of Pesticide Programs should:

- ▶ designate a specific unit of qualified scientific reviewers strictly dedicated to the overall review of biological pesticides from screening of applications to approval of registrations,
- ▶ streamline the review process for alternative pest control agents that sets mandatory deadlines for the review of and response to applications for field testing, registration, and amendment of registration of these products,
- ▶ couple a old chemical under special review with the application of an alternative pesticide for EPA registration,
- ▶ allow reduced risk pesticides to declare factual information about their safety and environmental compatibility on the label or in advertising,
- ▶ in cooperation with USDA's Extension Program, actively educate potential users about the benefits and proper usage of reduced risk pesticides to avoid resistance, and
- ▶ exempt users of registered alternative pest control agents from certain requirements for the purchase, storage, application, and disposal of synthetic chemical pesticides.

Congress needs to realign EPA's priorities to assure that farmers will have available new pesticides when they lose chemicals denied registrations and reregistrations. The U.S. Ninth Circuit Court of Appeals *Les v Reilly* decision on the Delaney Clause of the Federal Food, Drug, and Cosmetic Act (FFDC) has elevated the urgency for change. The following recommendations elaborate on our suggestions.

Designate a unit for review of alternative pest control agents The accelerated reregistration process mandated in the 1988 amendments to the Federal Insecticide, Fungicide, and

Rodenticide Act (FIFRA), has siphoned scientists away from the responsibilities for review of new biological products. EPA must employ well-qualified microbiologists, environmental scientists, and molecular geneticists who are uniquely able to evaluate the health and environmental impacts of biological products. The agency needs to assign these scientists, - perhaps buttressed by toxicologists experienced in assessment of residues, metabolism, and nontarget organism toxicity - the exclusive task of evaluating data requirements and submissions of both naturally derived and genetically engineered pesticides.

Streamline the review process for alternative pest control agent For reduced risk pesticides which have no adverse risks for mammals, birds, fish, or the environment, a review process should be established that requires the Administrator to notify the registrant if the application has been granted or denied within 180 days after receiving a complete application for registration of a reduced risk pesticide. Within 6 months, EPA should also notify the company if an exemption for tolerance under Section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a) has been granted or denied.

Couple old chemicals with alternative agents targeted to same pests The current pesticide cancellation process can extend for five years or more, consuming enormous resources and delaying the approval of safer alternatives. Understandably, farmers do not want to relinquish their tried and true weapons against pests. This situation immobilizes EPA regulators between a rock of economic hardship and the hard place of its mission to protect the public's health and environment. The result is inaction and delay. We propose a solution. When a chemical is under special review and the registration is highly likely to be denied or canceled, EPA should be required to couple the old chemical with an application for registration of an alternative product targeting the same pests. Provided all the data requirements have been met, EPA should redirect resources toward accelerating the review of the reduced risk

product. Won't this replace inaction with motivation?

Allow declarations about safety features on labels of alternative pest control agents

Alternative pest control agents which are found to present no risk to farm workers and are environmentally compatible should be able to declare these facts on the label. Many of these products, including Mycogen's microbial and fatty acid pesticides are no more toxic to humans than common household products such as shampoo and dishwashing detergent. These products break down quickly in the environment after providing their intended result. Yet, EPA regulations prohibit declarations of the environmental and health advantages of reduced risk pesticides on the label or in advertising.

Educate farmers about alternative pest control agents The USDA Cooperative Extension Program and EPA programs have often been the primary source of information on synthetic chemical pesticides, their proper handling and usage. These same channels of communication need to impart information about the potential advantages of using reduced risk pesticides and the proper application necessary to avoid pest-resistance from developing.

Exempt users of alternative pest control agents from requirements Pesticide users are barraged with compliance requirements for the purchase, storage, application, and disposal of pesticides as well as for the land and crops to which they are applied. For users of registered alternative pest control agents, EPA should review the appropriateness and necessity of requirements for RCRA reporting, worker protection standards, reentry intervals, and exemptions from residue tolerances. EPA should also consider approving disposal of these product containers in municipal landfills rather than hazardous waste disposal facilities. If granted, EPA should notify all pesticide users of the special advantages afforded reduced risk pesticides.

In summary, EPA's current registration process for biologicals is inefficient, costly, and unduly protracted. The current system is designed for chemicals and is **not** appropriate for biologicals which pose no toxicity to humans, mammals, birds, or freshwater fish. If EPA used the scientific personnel and a review timetable that are appropriate to reduced risk pesticides, the agency could free many resources unnecessarily used under the existing registration process. Large and small companies including Mycogen have invested heavily in research and development to provide American farmers effective alternatives that are environmentally compatible and safe for farm workers, animals, birds, and fish. The current EPA registration process has unfairly delayed the commercial availability of these products. As a result, as farmers lose some of their most trusted pest control agents, they are panicked about the production capability, especially for minor use crops. For many small companies, like Mycogen, investors get restless. The availability of joint venture funds is drying up for industries that appear to be strangled by regulatory ineptness and inefficiency. Let's not let a growth industry that is good for the American farmer, the public, and the economy move off shore, when some simple changes in the registration process for alternative pest control agents will certainly bring more of these products to market. If Congress and this Administration makes a commitment to expedited registration of reduced risk pesticides, research and development will intensify and both new and old companies will bring alternatives to the market.

RISKS AND BENEFITS OF PESTICIDES

WEDNESDAY, JULY 14, 1993

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON DEPARTMENT
OPERATIONS AND NUTRITION,
COMMITTEE ON AGRICULTURE,
Washington, DC.

The subcommittee met, pursuant to call, at 10 a.m., in room 1302, Longworth House Office Building, Hon. Charles W. Stenholm (chairman of the subcommittee) presiding.

Present: Representatives Sarpalius, Dooley, Inslee, English, Volkmer, Holden, Lambert, Smith of Oregon, Gunderson, Allard, Barrett, and Ewing.

Staff present: Joseph Muldoon, associate counsel; Julia M. Paradis, assistant counsel; Gary R. Mitchell, minority staff director; William E. O'Conner, Jr., minority policy coordinator; John E. Hogan, minority counsel; Dale Moore, minority legislative coordinator; Glenda L. Temple, clerk; Stan Ray, Rob Wight, James A. Davis, Curt Mann, and Pete Thomson.

OPENING STATEMENT OF HON. CHARLES W. STENHOLM, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. STENHOLM. I will call the Subcommittee on Department Operations and Nutrition to order.

This morning we will continue to focus the subcommittee's attention on the risks and benefits of pesticide use in U.S. food production, in our ongoing and sincere effort to help identify and address legitimate concerns relating to the use of pesticides.

The process of determining risks from the presence of pesticide residues in the diet is complex and imprecise. A variety of assumptions must be made; most of these are conservative and the assumptions may be based on both scientific and philosophical grounds.

Many recognize that there are inherent risks as well as benefits involved in pesticide use. Assessing risks and benefits is a cornerstone of food safety policymaking and is useful as a regulatory tool, yet it means different things to different people.

As I have said before, pesticides serve a tremendous benefit to society, which many of us take for granted. But with that said, and as a farmer in real life, I don't want to use any more pesticides than I have to—first of all, because the stuff is terribly expensive, but most important of all, I want to trust and expect that the pesticides I do use, in accordance with the label, are scientifically

proven to be effective without creating unnecessary risks to myself, my family, my neighbors, and the rest of society.

It is the responsibility of this subcommittee to identify areas where policy decisions can be made to decrease any health risks to consumers and increase public confidence in the food production sector, while maintaining the abundance and variety of foods available.

Any reauthorization of the Federal Insecticide, Fungicide, and Rodenticide Act, the legislative authority over which this subcommittee has jurisdiction, will encompass and be deliberated on principles surrounding the risk assessment issue.

With that, I look forward to all of your testimony today. I thank you for helping this subcommittee understand these complex issues so that we can begin the work of making necessary improvements in our current law.

I call the first panel, Dr. Reigart, Dr. Mattison, and Dr. Seiber. We normally operate under the 5-minute rule, but we are going to operate under the 10-minute rule today in light of your testimony. If you are normal, that means you have prepared for 5 and 10 will be just right for you. And also we won't try to cut you off.

We have two very small panels, but two extremely important panels for us to hear from today. With that said, we will call the first witness, Dr. Routt Reigart, chairman of the environmental health committee of the American Academy of Pediatrics, Washington, DC.

Dr. Reigart, welcome.

STATEMENT OF J. ROUTT REIGART, M.D., CHAIRPERSON, COMMITTEE ON ENVIRONMENTAL HEALTH, AMERICAN ACADEMY OF PEDIATRICS

Dr. REIGART. Thank you very much, Mr. Chairman and members of the subcommittee. My name is Routt Reigart; I am a professor of pediatrics at the medical university of South Carolina, where I am involved in the practice of general pediatrics and environmental medicine. I am the chairperson of the committee on environmental health of the American Academy of Pediatrics. Thank you for providing me this opportunity to speak today on the risks and benefits of pesticide use in our Nation's food production.

I come to speak to you today not as a professor or as an expert in environmental health, but as a representative of the 45,000 members of the American Academy of Pediatrics. Most of these members are practicing physicians who care for children and counsel parents on a daily basis. They are familiar with the concepts of risk assessment, but few are experts in performing formal risk assessments.

Most know a great deal about infant and childhood nutrition and are comfortable in providing counseling to the parents of their patients regarding appropriate nutritional practices. In this context, they expect experts and specialists in risk assessment to provide to them adequate information about the risk of pesticides and other chemicals in food to allow them to make appropriate recommendations for their patients. They would like to be able to say to their families, without qualification, "Your infant should eat a diet rich in fruits and vegetables. You need not be concerned about hazards

of pesticides in your selection of fruits and vegetables for your child."

In addition, when asked about the hazards of pesticides in food, pediatricians would like to make several additional affirmative statements, as follows:

1. "Pesticides used on our food have been tested for safety specifically to infants and children."

2. "The risk assessment process has taken into account the differences in children's diets, including diet selection and the higher caloric intake of infants and children relative to their body mass."

3. "The risk assessment process has taken into account the differences in the way children absorb, metabolize, store, and clear chemicals and other toxins from their bodies."

4. "The use of pesticides is regulated and regulations are enforced to ensure that pesticides are used in a safe and proper fashion."

5. "Foods which are available in the marketplace have been inspected to ensure that they do not contain pesticide residues which exceed approved limits which are based on an appropriate risk assessment process which has taken specifically into account risks to infants and children."

It is self-evident, but cannot be stated too often, that "children are not simply little adults." Attempts to extrapolate the risks of pesticides to infants and children based on adult risk assessment are doomed to fail, due to the many differences between children and adults. Furthermore, for chemicals persistent in the body, or for effects with long incubation periods, the 70 odd years of life expectancy for a child is a very long period at risk.

The American Academy of Pediatrics believes, given the available information on the risks of pesticides in the diet, that it is prudent to recommend that infants and children be provided a diet rich in fruits and vegetables. No known risk from pesticides presently outweighs the benefits of this healthful diet. The American Academy of Pediatrics also understands the benefits of pesticides to agriculture and accepts the proposition that it is possible to use pesticides in a fashion which is not hazardous to the health of infants and children.

It is not possible to use pesticides in such a fashion without knowledge of the actual risks to infants and children. At the present time it is clear that it is not possible to state that all pesticides have been evaluated for safety to children and their special needs. The American Academy of Pediatrics supports the development and funding of studies necessary to provide sufficient data to make risk assessment decisions which adequately protect the health of infants and children. The American Academy of Pediatrics supports regulation of the use of pesticides on foods and supports strong enforcement of such regulations. The American Academy of Pediatrics supports a strong program of inspection of foods to ensure that they are free of pesticide hazards.

It is my own view, based on my own experiences, that many families and physicians are very concerned that there is so little information regarding the safety for infants and children of pesticides in our food. Such concern will only be alleviated when the risk assessment and regulatory process clearly evaluates and assesses

risk to children of pesticides in their diet. Since children cannot make their own choices in food selection, they are potential unwilling victims of any errors we make in this process. We owe them the highest level of protection possible. They deserve the highest level of protection possible.

Thank you.

[The prepared statement of Dr. Reigart appears at the conclusion of the hearing.]

Mr. STENHOLM. Next witness will be Dr. Don Mattison, Vice Chairman, Committee on Pesticides in the Diets of Infants and Children, National Research Council, National Academy of Sciences, and dean, graduate school of public health, University of Pittsburgh, Pittsburgh, Pennsylvania.

Welcome, Dr. Mattison.

STATEMENT OF DONALD R. MATTISON, M.D., PROFESSOR, ENVIRONMENTAL AND OCCUPATIONAL HEALTH AND OBSTETRICS AND GYNECOLOGY; DEAN, GRADUATE SCHOOL OF PUBLIC HEALTH, UNIVERSITY OF PITTSBURGH; AND VICE CHAIRMAN, COMMITTEE ON PESTICIDES IN THE DIETS OF INFANTS AND CHILDREN, NATIONAL RESEARCH COUNCIL

Dr. MATTISON. Thank you very much, Mr. Chairman, and subcommittee members. I am the Vice Chairman of the National Research Council's Committee on Pesticides in the Diets of Infants and Children. The National Research Council is the operating arm of the National Academies of Sciences and Engineering. I am accompanied by Dr. James N. Seiber from the University of Nevada, who is also a member of the committee. We are pleased to be here to discuss our report, "Pesticides in the Diets of Infants and Children."

I also want to take this opportunity to acknowledge that the preparation of this report would not have been possible without the efforts of my colleagues on the committee and the staff of the Board on Environmental Studies and Toxicology and the Board on Agriculture of the National Research Council, National Academy of Sciences. The 14 members of this committee contributed an enormous amount of time as volunteers for what has proved to be an ambitious and complex study.

While pesticide use has increased the quality and quantity of foods in our diet, they are by design toxic to some living organisms. Because they are used in agriculture to control rodents, insects, fungi, nondesirable plants and so forth, pesticide residues are found on foods, and as a result, cause concern for human health.

Recognizing the benefit as well as the potential for human harm, laws have been enacted to protect human health while allowing the use of pesticides, as long as the risks to health are not unreasonable. There is concern, however, that as currently enacted these laws may not protect the health of all the diverse populations of the United States.

Recognizing that the regulatory focus may not be adequate, in 1988, Congress asked the National Academy of Sciences to convene a committee to examine the quality of the science used in characterizing risks to infants and children from the presence of pesticide residues in foods, and the methods used by regulatory agencies to

characterize those risks. The testimony here presents the findings of our report.

The committee began their deliberations with the acknowledgment that children are different from adults and then proceeded to examine if those differences would always result in increased risk. Characterization of risks involves understanding how a toxicant produces adverse effects and defining the exposure to that toxic substance. The topics examined in greatest detail for our analysis of risk assessment methods for infants and children included: Sensitivity to pesticide toxicity; the potential for long-term harm resulting from toxicity during growth and development; exposure of infants and children to pesticides in their diets; and methods used to calculate risks for infants and children.

After analysis of those topics and extensive deliberation, the committee recommends that the Federal Government: Change its scientific and regulatory procedures to specifically address potential risks to infants and children from pesticide residues in their diets; make immediate changes in the data gathered on food consumption patterns of infants and children and the analysis of those foods for pesticide residues; adopt a new method of risk assessment to more accurately characterize risks to infants and children from pesticide residues on their foods; and develop toxicity testing methods for pesticides which specifically address risks to developing infants and children.

In greater detail, our approach to this request examined the methods for characterizing risks to infants and children, and to conduct this analysis we used the framework for risk assessment which was outlined in a previous National Academy report, "Risk Assessment in the Federal Government." The framework has four steps: hazard identification, hazard characterization, exposure characterization, and risk characterization.

The first step, hazard identification, asks if the chemical of concern has been demonstrated to have adverse health effects on either experimental animals or in humans. Note that to protect the health of the public we would prefer to use data from animals and not require the demonstration of human disease from pesticides in our food.

To complete our analysis of methods and data, the committee collected and examined available data on toxicity testing of pesticides in young and developing animals. Unfortunately, there is little data specifically exploring the toxicological impact of pesticides on developmental animals, and for that reason we also used data on comparative toxicity of drugs.

The committee found that the changes that accompany growth and development are also accompanied by changes in the way the body handles pesticides or other chemicals. In some cases the potential for toxicity is greater in infants and children, and in other cases, the potential is less. Unfortunately, there is no simple way to characterize which compounds will represent greater hazards for infants and children than adults. However, where data is available, the toxicological differences between infants, children, and adults is generally between twofold and fourfold, and rarely as much as tenfold.

The second step, hazard characterization, explores how and where chemical acts to produce disease or illness. This step is especially important if we want to use toxicological data gathered in experiments conducted in animals to protect human health. While the biology of experimental animals is generally similar to humans, they can differ in critically important ways. These are of special concern with respect to developmental toxicity. For example, one fundamental difference between children and adults is the concern that if toxicity occurs during development, it can have long-term adverse health consequences.

As indicated, the committee noted that there were often quantitative differences between infants, children, and adults. However, there were few, if any, qualitative differences between developing animals and mature animals. So while children and adults may differ in the sensitivity of their responses to a pesticide, it was unusual for them to differ in the way they respond to a pesticide. This suggests that information on how a chemical works and produces toxicity in the adult may be useful in understanding these processes in infants and children.

The third step, exposure characterization; that is, to characterize who is exposed to a chemical, how often they were exposed, and how much they receive. To accurately complete this step, it is important to understand what children are eating and the pesticide residues on those foods. While our knowledge about the diets of infants and children as well as the pesticide residues on their diets is limited, this is the area in which the committee found the greatest difference between infants, children, and adults.

The diets of infants and children are substantially different from those of adults. Infants and children frequently consume a smaller number of foods than adults on a body weight basis. As a result of that, children frequently ingest single food items in amounts which are many times greater than adults. Indeed, the committee found that differences in consumption of single food items to be the most significant difference, with respect to potential for exposure to pesticides in foods, between infants, children, and adults.

The fourth step, risk characterization, combines all of the information gathered in the three previous steps and calculates the risks across the population for adverse health effects from the chemical or chemicals of concern. In our evaluation of this step the committee examined the methodology used by regulatory agencies for quantitating risks to infants and children.

The committee observed that the methods used were those developed for use with adult animals, and did not take into consideration the fact that infants and children are growing and developing, have different susceptibilities than adults, are exposed to multiple pesticides on a single food item, or to the same pesticide or pesticides that act by the same mechanism on different foods and by different routes. To remedy this and improve the risk assessment methodology, the committee suggests the following steps:

That data on unique dietary patterns of infants and children be gathered; data on pesticide residues in foods as eaten be gathered; and exposures to multiple different pesticides to the same foods or multiple different foods to the same pesticide be characterized.

In addition, because toxicity testing in developing animals is inadequate, it was not possible to directly calculate risks to infants and children using this methodology. However, we were able to use the method to calculate the exposures of infants and children to selected pesticides using the technique. On the basis of the information that I have summarized, the committee concluded that:

The susceptibility of infants and children is indeed different from adults—in some cases greater and in some cases less; infants and children differ from adults in their potential for unique exposure, with differences in exposure being the most significant difference between children and adults; it is necessary to develop additional information on toxicological characteristics of infants and children; and data on dietary exposures of infants and children to pesticide residues in foods is inadequate and requires immediate changes in Federal strategies for dietary surveys and analysis of those foods for pesticide residues.

The committee does believe, however, that the current regulatory framework allows an additional safety factor—which may be as large as tenfold—for risks of developmental concern, and believes that the use of the safety factor, where appropriate, provides adequate protection for infants and children.

The goal of our report has been to make a very good food supply even better. We have directed our report primarily to those who make decisions about pesticide use and those who regulate pesticides. The committee is not saying that parents should change their children's diets to avoid certain foods. We are also not saying that a particular food is dangerous for children and should be discarded. Parents should continue to emphasize a rich and diverse selection of fruits and vegetables in their children's diets.

The committee does believe, however, that basic changes are needed in the current regulatory system to ensure that foods eaten by infants and children are safe. The major conclusion of this study is that the risk assessment process used by the Federal Government for pesticides does not pay sufficient attention to the protection of the health of infants and children. The Government's current regulatory program does not recognize that children differ greatly from adults, not only in size but also in what they eat.

In summary, the committee believes that children deserve special consideration when it comes to pesticide regulation. By taking the recommendations we have outlined in our report, the Federal Government could go a long way toward ensuring that their health is not compromised by the food they eat.

Thank you very much, Mr. Chairman.

[The prepared statement of Dr. Mattison appears at the conclusion of the hearing.]

Mr. STENHOLM. Next we will hear from Dr. James N. Seiber, a member of the Committee on Pesticides in the Diets of Infants and Children, National Academy of Sciences, and the University of Nevada, Reno, Nevada.

Dr. Seiber, welcome.

STATEMENT OF JAMES N. SEIBER, DIRECTOR, CENTER FOR ENVIRONMENTAL SCIENCES AND ENGINEERING, UNIVERSITY OF NEVADA, AND MEMBER, COMMITTEE ON PESTICIDES IN THE DIETS OF INFANTS AND CHILDREN, NATIONAL RESEARCH COUNCIL

Mr. SEIBER. Good morning, Mr. Chairman and members of the committee. My name is James Seiber; I am a professor of environmental sciences and engineering at the University of Nevada, Reno; and until 1992 I was a member of the faculty and served in the dean's office of the college of agricultural and environmental sciences at the University of California-Davis. At UC-Davis, I specialized in pesticide residue issues and residue analysis.

Along with Dr. Mattison and 12 other scientists, I served on the Committee on Pesticides in the Diets of Infants and Children. My input was largely in the areas of residue data and exposure assessment, which are the areas that I wish to address this morning.

Clearly, for there to be a toxicological outcome, there needs to be exposure to the toxicant, and at levels which are above a no-effect level. Unfortunately, we do not know with certainty the precise exposure, nor the no-effect level—not for the average American and not for some populations of Americans such as infants and children. These uncertainties have led to the use of safety factors in regulating residue intakes, but the margin of safety provided by these factors may vary for population subgroups such as infants and children. It was a goal of our committee to determine what might be done to ensure that the risks were both minimal and also equivalent for all in the population.

One of the more time-consuming chores for the committee was to locate all the data bases of information that relate to residues in foods, and then place them on a common footing for interpretation. We were disappointed to find out that there does not presently exist a comprehensive data source on pesticide residues in foods. This is despite many millions of dollars and several thousands of samples collected and analyzed by our Federal and State agencies and by private industry. A computerized and standardized data base for pesticide residue data is badly needed, so that we can determine the exposure of the average American, and also subpopulations such as children, when issues of food safety arise.

Part of the problem is, the different analytical laboratories use differing procedures and these procedures catch differing numbers of the 600 or so registered pesticides and their breakdown products in the methodology. We felt there ought to be more standardization in this system for Federal and State labs and for private labs. Labs which conduct multiresidue analysis of foods, for example, should use the same or similar multiresidue methods, or at least ones which include the same cross-section of chemicals in their coverage. Labs should also handle such issues as detection limits, nondetects, and data averaging in the same or similar ways, to ensure comparability of data. Although our committee did not address this directly, it is my opinion that new and improved methods of residue analysis are possible, building in some of the latest developments in analytical chemistry.

Another problem is that much of the random surveys of residues are conducted on the raw agricultural commodity, and yet what we

want to know is the residue on food as it is consumed. Food processing and food preparation can dramatically alter—generally reduce—the residue on foods as consumed, but our committee found that data was not generally available documenting this point. An exception is infant formula for which all surveys to date show no significant residues are present.

We recommended that there should be a special market-basket survey designed around the diets of kids, and that more research be done on the effects of washing, peeling, cooking, et cetera, on residue levels. USDA's AMS program, which is 2 or 3 years old, is helping in this regard, and the efforts of food processors are helping even more, but still more needs to be done.

Finally, many of the foods most consumed by infants and children are not sampled very frequently, not enough to get a comprehensive picture of what chemicals and at what levels are in kids' diets. For example, the 18 foods most frequently tested in FDA surveillance program, include only 4 of the 18 major foods most consumed by infants and children. FDA has already begun to do more in this area, but even in its most recent report issued this month, far after our committee had its deliberations, reported on average about 12 orange juice samples collected and analyzed in the years from 1986 to 1991. There is also practically no data on residue intake from water used in preparing foods, which could add to residue intake from the foods themselves; and that is a particularly critical issue for children and infants because of their large dependence on liquid diets.

Thus, improved methods of data collection and analysis need to be incorporated in our agency procedures. Because people vary greatly in their consumption patterns and foods vary greatly in their residue contents, the convolution of distributions will provide information of greater specificity for population subgroups which may be at altered risk relative to the average. Chapter 7 of our report details this methodology.

We recommended further that the agencies focus more on combinations of chemicals rather than proceeding on a chemical-by-chemical basis in residue regulation. At least for some chemicals of a common mode of action, such as cholinesterase-inhibiting insecticides, our analysis showed that exposures as high as 10 times the reference dose could be calculated for a small but significant number of people, but unfortunately our present system of recording residue data, does not allow us to go back and make those calculations with any precision.

In conclusion, a safe American food supply can be made safer by changes in the way data are collected and analyzed. Our committee did not recommend changes in eating habits or food selection, and I think it is important to point out that we did not recommend restriction of use of specific chemicals. Generally, we felt that a lowering and a leveling of risk could be accomplished by the changes we recommend in data collection and regulatory procedures, particularly when combined with improvements in assessing toxicity of chemicals toward the young.

Mr. Chairman, there are a large number of agricultural scientists in Federal service and at our land-grant universities who are able

to address issues of food safety, along with efficient pest control in detail if provided with direction and resources.

Thank you.

[The prepared statement of Mr. Seiber appears at the conclusion of the hearing.]

Mr. STENHOLM. Thank you each very much for your testimony. I would plan to ask you to use the 5-minute clock on all members, including me, this morning. We will do a second and third round if necessary, but let's stay within the 5-minute rule.

The first question is, do you currently feel that you can recommend to parents that they can safely feed their children a variety of fruits and vegetables today?

Dr. Mattison.

Dr. MATTISON. Yes, the committee looked specifically for instances in which damage to infants and children, harm to their health, could be documented by eating foods as currently available in the United States. And we were unable to find any evidence of that.

There are some reports where there have been human health effects from the inappropriate use of these chemicals, but in terms of use as authorized, as appropriate, we were unable to find any evidence for harm to the health of infants and children.

Mr. STENHOLM. Thank you.

Mr. Seiber.

Mr. SEIBER. Mr. Chairman, we have a remarkable—an admirable record of safety with regard to pesticide use in this country, certainly when you consider the hundreds of compounds that are used and the acreage of crops that are treated. So my opinion is that our system works very well—surprisingly well already—and what we are doing in this report, I think, is suggesting ways to make that record even better.

So yes, I would recommend that they continue.

Mr. STENHOLM. Dr. Reigart.

Dr. REIGART. I myself—and the American Academy of Pediatrics has repeatedly stated in press releases and advice to pediatricians that we should continue to recommend a diet high in fruits and vegetables without any specific exclusions.

Mr. STENHOLM. I think it is very important at this stage in the hearing to read a paragraph from the executive summary of the study, "Committee on Pesticides in the Diets of Infants and Children," where it states the committee was not asked to consider toxicities resulting from exposure to microorganisms, bacteria, and viruses, or from other naturally occurring potential toxins. It was not asked to weigh the benefits and risks to be derived from a plentiful and varied food supply against the potential risk resulting from pesticide exposure. It was not asked to assess the overall safety of the food supply.

I think it is important that we focus on what you were asked to do, and that was to take a good look at our current system to see if it can be made better, particularly as it affects infants and children. One observation I would make for perhaps some comment—because each of you were once an infant and a child; whatever happened to you as an infant and a child has stayed with you until today. Everyone at this dais, everyone in this audience, was once

an infant and a child. Therefore, is there any evidence that points to what happens to us as a child or an infant carries forward into our adult life?

Or could we not expect to find—if there was something bad that happened to us because of our diet as a child, would it not carry forward into our adult life? Unless that which happened to us created a sickness or an illness during the time we, in fact, were children.

Dr. MATTISON. Mr. Chairman, you have asked, I think, a both very difficult but also appropriate question. It is that kind of a question that was at the heart of the deliberation that the committee focused its attention on.

We believe that there are influences that can occur during infancy and childhood, that may be unrecognized at that time, that can carry forward and, as a result, have an impact on an adult. That gets to the very heart of our deliberation. And in terms of trying to improve the process by which we look at risks, we spent a fair amount of time trying to characterize those systems that we thought potentially were most vulnerable to that kind of early influence, resulting in disruption of health later in life.

Those systems that we thought were potentially the most vulnerable included the immune system, the endocrine and reproductive systems, and the nervous system.

Now, in addressing those systems and in addressing the vulnerability of those organs for damage as a result of exposure, the committee also realized that the process by which we are doing that is a young and developing science itself. The structure that we use for characterizing risks in a quantitative way is not much more than a decade old itself. The questions that we are asking about risks to infants and children couldn't have been formulated in the way that we are formulating them now, a decade ago. And so in echoing the comments made by Dr. Seiber, what we were trying to do was move forward, to take a process that has already been effective at protecting health, and improving it.

Mr. STENHOLM. Any comment from the other two before I yield?

Mr. SEIBER. Mr. Chairman, I would point out one example that shows at least the potential, and that is for lead exposure among young folks. Now, part of that is dietary, part of that is not; but it has been pretty well-established that high lead exposures can lead to problems with mental development.

Now, fortunately some of that is reversible if you get the child off of the lead source early enough. So there is evidence from chemicals such as lead. Now, with pesticides, I don't think our epidemiology is clear enough to show that there have been problems in the past; and unfortunately it is not going to be clear enough to show that we have solved any problems when we make the improvements that we have recommended. So we are stuck with a situation of recommending that improvements, that we will probably never be able to prove with factual data, have occurred in the health of the population.

Dr. REIGART. I was about to use the same example Dr. Seiber used, which is lead toxicity, which clearly has long-lasting effects. It has been said, slightly tongue in cheek, that all disease is a product either of genetics or our environment. And if you think

about it, that is, in a sense, true. And our environment in childhood does infect us in many ways throughout our life and some of the examples influence endocrine and CNS dysfunction, which can result from early childhood exposures—certainly various forms of carcinogenesis.

There are estimates that over the last decade the rate of carcinogenesis in children has risen 18 percent; that is, there is an 18 percent increase in cancer in infants and children, which is probably best explained by a combination of environmental factors. Now, I am not suggesting it is caused by pesticides; please be clear about that. But there certainly are environmental effects on children which are, in a sense, later on in life, life-threatening or alter their performance as adults.

Mr. STENHOLM. Mr. Smith of Oregon.

Dr. SMITH of Oregon. Thank you, Mr. Chairman.

Dr. Mattison, I understood your statement—and clear it up for me if I am not correct—your statement indicates there ought to be a different attitude taken toward infants and children with respect to pesticides, yet I understood you to say that there is no evidence that current use as authorized has any impact upon infants and children.

Dr. MATTISON. That is a very good question. And it does get to this dichotomy that we have to deal with in protecting the health of the public.

One issue is, how much evidence do we need of damage to human health before we put into place regulatory strategies that we think will be beneficial? We believe that we can derive sufficient information from toxicological testing in experimental animal models to help us go a long way toward protecting the health of the public without requiring that their health be damaged. We also recognize that the levels at which we wish to protect the health of the public are often below our ability to measure accurately the impact of the regulatory public health protection strategy.

So—and in addition, if I could go back to what I commented on earlier, we are enhancing the development of our ability to characterize risks in populations.

Mr. SMITH of Oregon. All right. Thank you.

It occurred to me that in your report—and I am quoting from it—the very items that you were not asked to study are the very items this subcommittee needs an answer to.

For instance, the committee was not asked to consider toxicities resulting from exposure to microcosms, bacteria, and viruses, or from other naturally occurring potential toxins. It was not asked to weigh the benefits and risks to be derived from a plentiful and varied food supply against the potential risks resulting from pesticide exposure. And it was not asked to assess the overall safety of the food supply.

Those are the very reasons I think we are sitting here. So maybe we ought to go back to the drawing board.

I would like to have your assessment, Dr. Seiber, of the information we have against the backdrop of those things you were not asked to study, to give us some direction. In your mind, should we wait for this backdrop or do we have enough information to proceed?

Mr. SEIBER. Well, you have a very good point, Mr. Congressman. My own personal opinion is that one should be able to rank the various hazards that are associated with the food supply in some realistic way that would give guidance to people in their choice of diet and to agriculturalists in their growing and preparation of foods.

Microorganisms certainly are a well demonstrated example of a situation that can cause death. Microbial contamination has been documented to cause death in some cases. So that needs to be controlled. Natural toxicants are not as well documented, but there is a lot of suspicion and a lot of innuendo that if we, for example, changed our pest control procedures and did not use pesticides as much as in the past, that natural toxicant problem may become more of an issue, particularly if we genetically alter plants.

So that is not proven, and I am not taking a position on it one way or the other, but there is a big gap, a lack of information in that area.

Taking a larger approach to it with the fats in our diets, we have all heard about cholesterol and fatty foods and things of this type. These are real dietary problems that need to be addressed. So where do pesticide residues rank in this hierarchy of characterization of different things that exist in the food supply? In my own opinion, they are certainly not at the top, maybe not at the bottom either; but probably toward the bottom when you look at all the various risks that are associated with materials that are in the foods, and the use of foods and overuse of foods that are inappropriate, such as high-fat foods.

Mr. SMITH of Oregon. Would you agree basically with that statement, Dr. Mattison, that pesticides rank in that array near the bottom?

Dr. MATTISON. Yes.

Mr. SMITH of Oregon. Dr. Reigart, one final question. This is a quote from the American Academy of Pediatrics. They also understand by this quote, "the benefits of pesticides to agriculture," and I want to probe that for a minute simply because I want to ask you, is the cost of food a health consideration?

Dr. REIGART. It certainly can be. Everybody understands that if people can't afford food, they will suffer nutritionally, yes, sir.

Mr. SMITH of Oregon. So really maybe that statement should have been "benefits to the public." I mean, there is a connotation that if you improve the uses of some agricultural production, you improve agriculture. What we are really doing is increasing the benefits to people while we are improving agriculture. Would you not agree with that?

Dr. REIGART. Yes—well, you are certainly entitled to that interpretation, yes, sir.

Mr. SMITH of Oregon. Thank you.

Mr. STENHOLM. Mr. Holden.

Mr. HOLDEN. Thank you, Mr. Chairman. I would like to thank the panel for their testimony this morning; and I can assure you that the chairman and every member of this subcommittee wants to be sure that American infants and children are consuming safe food.

But I just have one question. There are many other countries whose pesticide regulations are nowhere near as strict as they are in this country. And I was just wondering, is there any credible evidence that infants and children in those countries are suffering more serious health problems than infants and children in this country?

Dr. MATTISON. I am not aware of any. And as a matter of fact, as a follow-up of the release of the report, we have been looking—I have been looking at ongoing epidemiological studies trying to characterize the impact of pesticides in high exposure groups. And have discovered that the National Cancer Institute has a long-term study looking at health effects in farm families, which will include characterization of infants and children.

Now, it will be about a decade before that study is finalized, looking specifically at cancer, risk of cancer from exposures. But that is the only—again, I am not aware of any data and that is the only study that I know of at the present time that could hope to answer in a high exposure group the health risks specifically associated with agricultural chemical use, predominantly focused on cancer.

Mr. HOLDEN. Dr. Seiber.

Mr. SEIBER. Yes, Mr. Holden. I can't speak directly to pesticide residues in foods in other countries, but certainly there are a number of pesticide-related illnesses and deaths from improper usage, poor packaging, poor application equipment, the lack of safeguards in applying chemicals. And these seem to be major problems in some of the other countries around the world.

My suspicion is, there probably is a residue problem. We don't see it in imported foods because we have good safeguards, but I think that for domestically grown foods that are consumed in those countries, I would have to wonder and probably predict there could be some problems with some of the chemicals that are being used.

Mr. HOLDEN. Thank you.

Dr. Reigart.

Dr. REIGART. Certainly there are many instances of injury to children in other countries from misuse of pesticides or pesticide used differently from in this country.

But to answer your question just one step further, I, specifically, in another job that I have, consulting the National Institute of Environmental Health Sciences, have suggested that one of the approaches to assessing the risk to children of pesticide residue would be to perform epidemiologic studies in highly exposed populations. And one of the options in choosing such populations would be to go to countries that have less stringent regulation, as well as to look at children who in this country might have increased exposure.

So I have specifically suggested such studies to give you that information.

Mr. HOLDEN. Thank you.

Mr. STENHOLM. Mr. Allard.

Mr. ALLARD. Thank you, Mr. Chairman. I would like to follow up on Dr. Seiber's comments on laboratory procedures and lack of standardization.

Just to review that, you have in your comments this quote: "Part of the problem is that analytical laboratories use differing procedures, catch differing numbers of the 600 or so registered pes-

ticides, and their breakdown products in their analysis and varying in their way of reporting data." It seems to me that the validity of this whole process relies on the validity of the information that we are getting from the laboratories. I wonder if perhaps maybe our first priority shouldn't be working on getting the scientists to agree so that we can get some standardization of data.

I am wondering if the three panelists would comment on that.

Mr. SEIBER. The only addition I would make to the statement is that even the Federal laboratories that are involved in this—for example, Food and Drug Administration laboratories—use different procedures and use them in different sequence in their various laboratories around the country. They have a good reason for doing that, because they each examine a different part of the food supply. But even at that level, there is not complete standardization and uniformity. It seems to me that uniformity would be desirable.

By the way, I didn't mean to imply the data was not of good quality. I just meant the procedures won't necessarily catch the same chemicals. And I think the real concern is that some chemicals may be passing through the safety net and going undetected. So in that regard I would like to see the procedures broadened and made more uniform.

Mr. ALLARD. In that light, isn't that more of a laboratory problem than it is anything else? And how do we get all the scientists to agree on some standardization of which procedures are the best?

Mr. SEIBER. An OTA study, Office of Technology Assessment study, in the late 1980's came to the conclusion that we ought to improve our residue methodology. You have to realize that the methods were developed in the 1960's and early 1970's, and what we do now is add new chemicals on to older methods. And they simply can't handle the new structures that are coming along.

So I think there ought to be a new look at it in a radical way, where we actually start over again and develop methods that are more compatible with the advances in chemistry and instrumentation that have come about in the last few years. That is my own personal belief, that there should be that kind of overhaul of the residue testing system.

Mr. ALLARD. You think that should be a top priority in addressing this problem?

Mr. SEIBER. I think so.

Mr. ALLARD. If not the top, at least one of the top priorities.

Mr. SEIBER. I think we could both broaden the coverage and also do it at less cost. The procedures we use right now are quite expensive and I think there is information that would suggest we could lower the cost with a redesign of residue analytical procedure. Personally, I feel it ought to be top priority because we are going to be collecting our 20,000, 30,000 samples a year and we may find we can do a better job with those samples at less cost if we put the money up front by investing in improved methodology.

Mr. ALLARD. Thank you. I see everybody sort of shaking their heads in agreement. Is that true? Do you all agree with those comments?

Dr. MATTISON. Mr. Allard, yes. We identify characterization of exposure as the one area in which children differ most significantly from adults. To more completely characterize those differences in

exposures depends primarily on two advances, first in the foods that are eaten by children; and the second, the characterization of the residues on those foods. And in the absence of consensus on validated analytical techniques, that critically important step is going to remain a morass.

Mr. ALLARD. It seems to me that right now we are looking, or legislation has been introduced that has some specific figures and limits in it. I am not sure it is advisable until we kind of get some standardization on the laboratory process, so we can get reliable results, how advisable it would be to have that in specific legislation.

Mr. SEIBER. The legislation you are referring to would set specific detection limits, for example, for methods that are used in residue analysis?

Mr. ALLARD. What I understand is that they are attempting to set some specific figures in there and specific targets.

I think I would have some concern about that, considering the nature of the changes in procedure that we have in our analytical line here, suggesting it needs to be improved; and it seems to me that would not be a good approach.

Mr. SEIBER. I would agree. I think there ought to be a meeting of the minds or a work group established with people who are knowledgeable and leaders in the field of residue chemistry to recommend what is feasible now and what might become feasible down the road, instead of legislating particular detection limits and methodologies. That would be my opinion.

Mr. ALLARD. Thank you.

Thank you, Mr. Chairman. I see my time has run out.

Mr. STENHOLM. Mr. Dooley.

Mr. DOOLEY. Thank you, Mr. Chairman.

Dr. Seiber, I appreciate your comments on the need for standardization, and it sounds like you are an advocate for some type of reform of our residue testing protocols. I would also like to gain an understanding in terms of our risk assessment with the testing protocols that include a heavy reliance on the maximum tolerated dose in order to try and make some term—or some analysis of what particular risk a chemical might pose.

Do you have any ideas on how that could be changed, or is there a need for it to be changed?

Mr. SEIBER. I would like to refer that question to one of my colleagues.

Dr. MATTISON. Mr. Dooley, the National Academy of Sciences has directed a fair amount of its attention to risk assessment methodology. This is one of a group of reports that have explored it. One of our recent reports looked specifically at the role of testing at the maximum tolerated dose in terms of the design of toxicological testing protocols. And I think the best way of describing it, the outcome of the deliberation of that particular committee was that there was no consensus on the advisability of continuing or discontinuing toxicological testing at the maximally tolerated dose.

The members of that committee recognized that using very high levels of chemicals, maximally tolerated dose exposures, often produces in the animal models that we use a disturbance in the way that they respond to that chemical or a difference in the response

of the organism to the chemical in terms of the development of disease.

Mr. DOOLEY. My concern is—and I have had the chance to read a lot of testimony, and I agree wholeheartedly that we ought to be doing a better job of assessing what the dietary intakes of children are. My concern though is, as we move forward to try to identify what the real risk is, and we are going to continue to rely on a testing protocol which is based on this MTD which—there is no consensus, as you said, that we ought to even continue with this—and what appears to me is a potential, as we use it on developing animals, that the problems and shortcomings could be even further pronounced.

Are we, in fact, going to be getting data and getting risk assessments that are even less sound in quality?

Dr. MATTISON. That is a very good question, and I think the most appropriate way of going beyond the committee's recommendation would be very much in the same line as the analytical methods suggestion, and that is that a group of toxicologists be convened to develop a consensus of the appropriate methods for testing, toxicological testing for issues of developmental concern; and that if backing away from the maximally tolerated dose or if modifying the number of doses that are used in these studies, to put the dose range into a region that is compatible with human exposures, were agreed upon, that then should be carried forward in the regulation.

Mr. DOOLEY. From your perspective, what do we have to do to make that happen?

Dr. MATTISON. I think a group of individuals needs to be brought together that are experienced in and understand the special vulnerabilities of the central nervous system, the immune systems, and the endocrine systems; that they be tasked with working out, either within the confines of the regulatory framework of the United States or more broadly in a global regulatory framework, what are the appropriate test methods, what are those methods that take account of the normal biology of the experimental animal and how they can be translated into humans.

I think it can be done. I think it needs to be done, and I actually think that second to or parallel with the development of analytical techniques, this is something that has to be given substantial attention.

Mr. DOOLEY. Mr. Chairman, I mean, I couldn't agree with this more; and anything that this subcommittee can do to facilitate that effort, I would be real supportive.

And I am going to close with just a kind of editorial comment. My concern is that when we move forward with taking actions that might be precipitated by the report, we in fact might be requiring the expenditure of significant resources by both the private and the public sector in order to try to alleviate a level of risk which is going to siphon funds away from applications which could have a far more beneficial impact on improving children's lives, whether it be finding ways to improve home environments, finding ways to improve nutrition in general, finding ways to eliminate other risks out there. And I am concerned about us marching down this path which could result in tremendous increase in fund expenditures by both the private and public sector, when there might be a whole

different approach in which those funds could be utilized more effectively.

Thank you, Mr. Chairman.

Mr. STENHOLM. Mr. Gunderson.

Mr. GUNDERSON. Thank you, Mr. Chairman, and let me begin by thanking all three of you, not only for being here today, but also for what you have been doing and what you have been saying. As I sit here and listen to your testimony and look around this room, I am struck and literally impressed by the fact that you have brought a great deal of intellectualism, a great deal of calm, and a great deal of reason, to an issue that could be totally consumed by emotionalism and headlines.

My concern, however, in listening to your report, is trying to figure out from that side of the table to this side of the table, "Where do we go from here?" Because I think this also has the potential of a great news story today that doesn't go much further, very frankly. As I look at your recommendations and as I listen to your answers to my colleagues, it seems to me that you suggest that before we go further there has to be a whole series of scientific protocols established and pursued to really define the next step. Is that correct or not?

Dr. MATTISON. The report makes both short-term and long-term recommendations. And there are things that we think can be done immediately. For example, better data on what children eat, better data on the pesticide residues, recognizing that there may be some flaws in or some disagreements about those analytical techniques. Those are issues that can be addressed immediately, and based on that information, can put the regulatory agencies in a position to feel either more comfortable or more anxious about how quickly they need to respond with some of these more academic areas of interest that we have laid out.

Mr. GUNDERSON. The next obvious question we face though is the interaction with EPA, primarily on reregistration.

My question is, How much interaction have you had with EPA since the publishing of the report and to what degree are you knowledgeable that EPA is going to try to pursue most of these recommendations through the traditional regulatory and review process?

Dr. MATTISON. We have briefed and interacted with senior staff at the EPA. My impression from those discussions—and I will also turn to my colleagues—is that they were very appreciative of them and they were looking for ways to begin implementing them as soon as they could, including strategies for identifying the money to buy copies of the report to distribute to their staff.

Mr. GUNDERSON. We will get to that point. Any other comments?

Mr. SEIBER. I would just follow up on that and say that EPA participated to a certain extent in the deliberations of the committee. EPA staffers served as consultants to the committee, made valuable inputs, and some of the things that we recommended have already been put in place or at least the wheels are turning to put them in place at EPA.

As Dr. Mattison mentioned, some of our recommendations can be put into place fairly readily without, we think, a large expenditure, perhaps no expenditure of funds, just by diverting present effort.

For example, foods could be sampled more that are consumed by children and infants just by redesigning the sampling strategy, and among the 20,000 samples that FDA takes, there ought to be enough slack to make that kind of adjustment. So in that regard, I think some movement can be made without large expenditures.

Development of new toxicity tests with young animals could be an expensive proposition, either for industry or for the Government.

Mr. GUNDERSON. Is it possible for you to make recommendations to this committee, because it is obviously an emerging and evolving science, as to which of your recommendations ought to be, pursued by the regulatory and enforcement agencies? And which, if any, ought to be pursued from a legislative perspective? As I look at a lot of your recommendations, I frankly don't see them as legislative language. Are you all willing and able to try to give us some advice, if not today, down the road on that particular issue?

Dr. MATTISON. Mr. Gunderson, my impression is that everything that we are recommending is capable of being done in the current—within the confines of the current regulatory framework.

Mr. GUNDERSON. All right.

Dr. REIGART. I wasn't the policeman of the committee, but I certainly would support that. I think, clearly, as more information is developed, as the science improves, as there is coordination between scientists, there may be need for legislation later on. But right now I don't perceive any major legislative thrust in this area.

Mr. SEIBER. One thing, Mr. Congressman, that occurred actually a few days before our report was released was that the three main agencies that are involved in pesticide regulation started a dialog which we think is long overdue. And if that kind of momentum continues forward, only good things can happen. So we think things are happening the way we would like already.

Mr. GUNDERSON. I am out of time, but I desperately hope at least one of the reporters in the room will include the line "No new legislation requested." Thank you very much.

Mr. STENHOLM. Mr. Sarpalius.

Mr. SARPALIUS. Thank you, Mr. Chairman.

All of you talked about how one of your concerns is the way that we regulate and inspect our foods is that it is geared more toward adults and less as far as how it affects children. And, Mr. Seiber, you talk about your market-basket survey, you talked about how we don't emphasize enough on the water and cooking and preparation of food and what effects that has on it. You also talked about how we ought to take more samples of prepared food.

Can you elaborate a little more about what you think we need to do to emphasize that we pay more attention, take more samples on prepared food and emphasize more tests on children versus adults?

Mr. SEIBER. I think in the overall scheme, that "more" is probably not the correct word. I think it is a redirection of resources.

Among the samples that are taken, I believe there is plenty of slack to redirect and maybe collect more market-basket prepared foods for analysis and fewer of the green peppers and broccoli that tend to dominate present residue testing. So the market-basket idea for kids is not a new idea, and in fact the Food and Drug Ad-

ministration again has already started to implement this even before the report came out, by again redirecting effort in their present sampling and analytical procedure.

So I don't see a lot more samples. I think it is more a question of how you allocate your present sampling strategy.

Mr. SARPALIUS. What you are saying is, all of you recommend we ought to focus more on taking samples that affect children, versus samples that affect adults. Am I correct?

Dr. MATTISON. Yes.

Mr. SEIBER. That is correct.

Mr. SARPALIUS. And would you suggest that in those, the types of food that we examine, that we are talking about prepared food versus raw food?

Dr. MATTISON. Yes, that is correct.

Mr. SARPALIUS. OK.

Dr. MATTISON. Basically, we would recommend that more information be available on foods as they are consumed by infants and children. We also recognize that regulatory agencies may need to change their sampling strategies over time.

At some point in time they may recognize that they have sufficient data on infants and children and want to turn to other special populations. They need to have the flexibility to do that.

Geriatric populations may at some point be a concern. And so the ability to choose the sampling strategy to focus on appropriate and different populations overtime is something that the regulatory agencies need to be encouraged to do.

Mr. SARPALIUS. One thing that I found interesting in what you said, Dr. Seiber, about preparing food where you talked about water—I mean, in this country we probably—the American taxpayers probably get the best buy for their dollar on what we invest on food safety, clean water, clean environment.

Some of my colleagues were talking about how do we compare to other countries around the world. Well, there is no comparison when you compare the emphasis that we put on trying to have clean water and clean food. It is a great buy for the American people. And I think that we do try to do the best job that we can. But there is no question that I think you are absolutely right that we need to probably focus more on prepared food for children and less on prepared food for adults.

Dr. Seiber, in your written testimony—I didn't hear you talk about it yet—you mention in your written testimony about new techniques in monitoring chemicals. You said earlier about how we ought to focus more in that direction.

Tell me what are some of these new techniques?

Mr. SEIBER. Well, you have brought up a good point, Mr. Congressman. In our water analyses, mass spectrometry is used almost exclusively in our Federal laboratories. But in food residue analysis, mass spectrometry is used very rarely. So there is an obvious example where we need to bring in the latest that analytical chemistry has to offer. Yes, the mass spectrometer is more expensive, but it gives you better quality and a broader coverage of chemicals that are present.

The marketing companies, the grocery store retailers, have retained companies that rely more on mass spectrometry in their

testing than our own Federal and State agencies who do the testing for the public. So certainly it is possible, and that is one example.

Another example is immunoassay, which promises the possibility of screening larger numbers of samples at less cost. Immunoassays are not more accurate, they are not necessarily more sensitive, but they can screen samples. And they are already being used for water analysis. They need to be used more for food analysis.

So there are some examples out there already.

Mr. SARPALIUS. I see my time has run out. Thank you.

Mr. STENHOLM. Mr. Ewing.

Mr. EWING. Thank you, Mr. Chairman, and thank you to the panel for your testimony today.

The National Academy of Sciences committee recommended some procedural changes to risk assessment and suggested exploration of alternative methods to assess risk. There have been those who have seized upon that as a call by the National Academy of Sciences for an overhaul, total overhaul of the system. And I think you have answered that.

But very directly, is that so or not?

Dr. MATTISON. I think that the risk assessment methods that are currently available form the foundation for extension and improvement. The areas of improvement include a better understanding of developing animals and their sensitivity and a better understanding of the exposures that are encountered by infants and children.

Mr. EWING. And not a general overhaul of the whole system?

Dr. MATTISON. No. I think the current methodology is quite robust. It has withstood a decade of use, and I think forms a very rational basis for assessing risks to human populations.

Mr. SEIBER. Mr. Congressman, I serve on another committee on risk assessment for hazardous air pollutants with the academy, and that perhaps gives you an example that the academy is looking at risk assessment across the broad spectrum of exposures, not just residues in foods.

In that particular committee, we have dealt a lot with the uncertainty in risk assessments and some of, quite frankly, the imperfections in present risk assessment in an effort to try to improve it—not to totally do away with it, but simply to improve it and make it more precise. And we have also recommended that we look at end points other than cancer. We feel that a lot of our present risk assessment is cancer driven and that there are other effects out there that need to be looked at.

So, yes, there are improvements that need to be made and the academy is very active in pursuing these.

Mr. EWING. Doctor.

Dr. REIGART. I wasn't a member of that committee, so I probably shouldn't answer that question.

Mr. EWING. I guess to follow up then, you feel that there is progress being made and that we are looking in new and different directions and that we can pretty much do that under the framework of our current system?

Dr. MATTISON. Yes. I believe it gives the agencies a lot of flexibility. I believe that there is a strong scientific base for the framework as it is currently sustained. I believe that the attention to a range

of alternative end points beyond cancer is the appropriate developmental process for the system.

Mr. EWING. In a different vein, metanalysis statistical method is one of the report's recommendations. And how is this statistical analysis system viewed by the scientific community relative to its application to risk/benefit analysis?

Dr. MATTISON. Metanalysis is a technique for combining data from a broad range of individual and different studies to try to enhance our ability to characterize impact or lack of impact on a population. It has been developed over the past 10 to 15 years, is used predominantly by epidemiologists, and is considered quite favorably as a technique for combining information from different and disparate studies.

Dr. REIGART. I can speak to that as an epidemiologist.

Metanalysis is a very strong tool. It can suffer if the studies combined are so different that they should not be combined, but with reasonably comparable methodology you can produce very strong inferences by combining studies with metanalysis. It is a very good technique.

Mr. SEIBER. Mr. Congressman, the present committee report was peer reviewed by a large number of people, and we had their input, but the actual publications on the methodology in our report are still forthcoming. So we will see peer review in that process among the authors of those particular sections of our report. So that is yet to come.

Mr. EWING. Just one final follow-up to yours, Doctor.

Your comment is, the capability of accurately assessing the multitude of combinations of food and varying levels of pesticide application, geographic distribution and all of that, that is a problem in this system, or can be?

Dr. REIGART. It sure can be. I think the point of the American Academy of Pediatrics is that we have attempted to do this for adults, but we really have insufficiently attempted to do this for children. So that even though there are pitfalls and difficulties, we owe it to our children to try and assess the risks to them.

Dr. MATTISON. In agreeing with your statement, the committee recognizes that when children eat foods, they are exposed to multiple residues on an individual food and over the course of a day are likely to be exposed to multiple different chemicals on all of the foods that they eat. The risk assessment techniques that are used need to characterize and take account of those multiple exposures, not only exposures on food, but in the water that they drink and bathe in, and in the other exposures that occur in the other environments that they are in—air, dirt, rugs, dust.

Mr. EWING. Thank you very much.

Mr. STENHOLM. Ms. Lambert.

Ms. LAMBERT. Thank you, Mr. Chairman. I ask unanimous consent to have a prepared statement added to the record.

Mr. STENHOLM. Without objection. All members may have prepared statements placed in the record at this point.

[The prepared statements of Mrs. Clayton, Ms. Lambert, Mr. Roberts and Mr. Smith of Oregon follow:]

EVA M. CLAYTON
1ST DISTRICT, NORTH CAROLINA

HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-3301
(202) 225-3101

Congress of the United States
House of Representatives
Washington, DC 20515-3301

STATEMENT OF REP. EVA M. CLAYTON
SUBCOMMITTEE ON DEPT. OPERATIONS & NUTRITION

14 JULY 1993

Thank you, Mr. Chairman, for holding this hearing as one of many in a series of pesticide-related hearings. I know that your interest in this issue runs deep, and I appreciate your concerns as they relate to the health of American agriculture.

The food production capabilities of the United States, as well as its efficiency, has long been the envy the world. Much of our nation's strength has been our ability to provide for agricultural self-sufficiency. Our international prominence as an agricultural producer is second to none. Consequently, potential health risks created by pesticides

are of great concern to me.

We all recognize the positive benefits and the risks which accompany pesticide use. I am also familiar with the problems with pesticide registration. However, it may be possible that the methodology we use for risk-assessment may need to be re-examined. The recent National Academy of Science (NAS) study, Pesticides in the Diets of Infants and Children, indicates that greater care must be made to take into account the vulnerable segment of our population that children represent.

In the big picture, appropriate risk-assessment will not only assist our farming community, but it will benefit the entire agriculture related industry as consumer confidence is improved. I am confident that we are taking the right steps in this direction.

Again, thank you Mr. Chairman for your persistent interest in this crucial issue, and I welcome the panelists to the Subcommittee.

BLANCHE M. LAMBERT

1ST DISTRICT ARKANSAS

1204 CONLAWORTH BUILDING
WASHINGTON, DC 20515
202-225-4076DISTRICT OFFICE
615 SOUTH MAIN
SUITE 211
JONESBORO, AR 72401
501-972-4800
800-866-2701

Congress of the United States
House of Representatives
Washington, DC 20515-0401

STATEMENT OF THE HONORABLE
BLANCHE M. LAMBERT
BEFORE THE HOUSE SUBCOMMITTEE ON
DEPARTMENT OPERATIONS AND NUTRITION
JULY 14, 1993

COMMITTEE ON ENERGY AND COMMERCE

SUBCOMMITTEE ON ENERGY AND POWER

SUBCOMMITTEE ON HAZARDOUS MATERIALS

HAZARDOUS MATERIALS

VICE CHAIRMAN

COMMITTEE ON AGRICULTURE

SUBCOMMITTEE ON DEPARTMENT OPERATIONS
AND NUTRITION

COMMITTEE ON MERCHANT MARINE

AND FISHERIES

SUBCOMMITTEE ON ENVIRONMENT AND NATURAL
RESOURCESSUBCOMMITTEE ON COAST GUARD
AND NAVIGATION

THANK YOU MR. CHAIRMAN. ONCE AGAIN I APPRECIATE YOUR DEDICATION TO BRINGING THIS IMPORTANT ISSUE BEFORE THIS SUBCOMMITTEE. AS A FRESHMAN MEMBER, THESE HEARINGS HAVE PROVIDED ME WITH A GREAT DEAL OF INSIGHT REGARDING OUR FEDERAL PESTICIDE LAWS AND I LOOK FORWARD TO LEARNING MORE TODAY.

DUE TO THE DECISION REGARDING THE DELANEY CLAUSE THIS PAST SPRING, THE DEBATE OVER PESTICIDE USE AND PUBLIC SAFETY HAS BEEN A POPULAR TOPIC AND AS A RESULT OF THAT, THE WAY THAT THE CONGRESS AS WELL AS THE EPA SET POLICY HAS BEEN CLOSELY SCRUTINIZED. TO A LARGE DEGREE, I BELIEVE THAT THIS HAS BEEN A HEALTHY DEBATE. WHILE THE PUBLIC SHOULD BE AWARE OF THE RISKS THAT ARE INVOLVED IN PESTICIDE USE THE BENEFITS THAT ARE ACCRUED SHOULD BE DISCUSSED AS WELL. IT IS MY HOPE THAT THE RESULT OF THESE HEARINGS WILL BE POLICY BASED ON SOUND SCIENCE THAT WILL MAINTAIN PUBLIC CONFIDENCE IN OUR FOOD SUPPLY.

I LOOK FORWARD TO HEARING TESTIMONY FROM OUR WITNESSES.

The Honorable Pat Roberts
 Hearing Statement
 Dept. Operations and Nutrition Subcommittee
 July 14, 1993

RE: Review of public health risks and benefits of pesticides

Thank you Chairman Stenholm and Mr. Smith for calling today's hearing on the risks and benefits of pesticides used by farmers in their efforts to provide U.S. and foreign consumers a wholesome, abundant supply of food. Reasonable, scientific assessment of the risks and benefits of pesticides and their uses is the foundation this Committee has long sought as a basis for improving federal food safety statutes and regulations.

By working with the best information science can provide, and by incorporating into the regulatory process the maximum amount of flexibility that political will and common sense will allow, we can ensure pesticide policies that:

- maintain a healthy food supply encompassing a wide variety of commodities and products;
- decrease identifiable health risks to consumers, as well as those using pesticides in the food production operations; and,
- increase public confidence in America's food supply.

While we must agree that pesticides, by their very nature, do pose risks -- especially if used improperly -- we also need to agree that the benefits of pesticide use go well beyond simple economic benefits to farmers. Consumers benefit from lower food costs and a wider, more affordable variety of foods essential to a balanced diet. And, the public in general benefits from pesticides that controls disease-carrying pests, bacteria, viruses, fungi, etc.

The recent report released by the National Academy of Sciences, "Pesticides in the Diets of Infants and Children," adds additional pieces to this complex, often confusing puzzle of assessing the risks and benefits of pesticide use. The report states that:

- Pesticides, which are widely used in US agriculture production, have improved crop yields and increased the quantity of fresh fruits and vegetables in the diet, thereby contributing to improvements in public health.
- FIFRA and the Federal Food, Drug, and Cosmetic Act (FFDCA) are the two primary statutory foundations used by the federal government to regulate the exposure of pesticides (residues) in the food supply.
- Residues are regulated through different mechanisms, but the single, most important mechanism is "tolerances" -- defined as the legal limit of a pesticide residue allowed in or on a raw ag commodity, or where appropriate, on processed foods. Tolerances are established for any pesticide used on any food crop, and are designed to reflect the highest residue concentrations likely under normal conditions of use.

Roberts, 7-14-93, page two

One of the reasons for the study, which began in 1988, was to review the risk assessment methodologies in place that base risk exposure on evaluations covering the average U.S. population, and determine if further considerations were needed to specifically consider infants and children in establishing tolerances, etc. The NAS committee did conclude that both quantitative and occasionally qualitative differences in toxicity of pesticides between children and adults.

The NAS committee also found that quantitative differences in toxicity between children and adults are usually less than a factor of ten-fold, and that infants and children differ both qualitatively and quantitatively from adults in their exposure to pesticide residues in foods. Differences in exposure were generally a more important source of differences in risk than were age-related differences in toxicologic vulnerability, generally referred to as the "front-loading" issue.

Certainly, these findings help confirm and expand the general understanding veterans of the food safety debates have relative to resolving the question of risks versus benefits. But, there are some missing pieces that this Subcommittee can hopefully add to the puzzle with the expert testimony of today's witnesses.

For example: What health risks are prevented by the use of pesticides in food production and processing? There are several potential food supply toxins -- such as bacteria, viruses and fungi -- that prudent use of pesticides and pest control methods help control.

Also, I am concerned that some of the armchair analysts of the NAS report are concluding that the entire system needs to be changed immediately. However, in my review of the report's recommendations and conclusions it seemed the NAS committee basically indicated that substantial gaps exist in the data available to accurately assess risks, and that these data gaps needed to be filled before the Administration and Congress embark on a wholesale changing of the system.

The bottom line is that this Committee, and others with the responsibilities related to the statutory and regulatory framework that governs pesticide use in the United States, must ensure implementation and maintenance of a risk assessment and benefit analysis process that follows sound, rational scientific principles with the necessary flexibility to make common sense changes to the process as new methodologies and technologies become available that can provide more efficiency and accuracy to risk assessment procedures.

And further, our goal must remain ensuring the ability of American farmers and ranchers to provide this nation, and a troubled and hungry world, a wholesome, sufficient, and affordable supply of food.

STATEMENT OF
ROBERT F. SMITH
BEFORE THE
SUBCOMMITTEE ON DEPARTMENT OPERATIONS AND NUTRITION
JULY 14, 1993

Mr. Chairman, I would like to thank you for calling this hearing today. I would also like to commend you for the chosen theme of this proceeding, the review of the risks and benefits of pesticides.

Too often, in both the print and broadcast media, in the regulatory agencies of our federal, state, and local governments, in the courts, and here in Congress, we focus our attention only upon those aspects of pesticide policy which have potential for risk.

Science, and our everyday experience, tells us there are benefits associated with risks in the use of pesticides. A sound pesticide policy, one which ensures public health, maintains consumer confidence, and provides productive tools for agriculture, will require us to weigh risks and benefits.

The scientific community will rarely give us refuge from this responsibility by presenting clearcut answers. The National Academy of Sciences recent report on Pesticides in the Diets of Infants and Children is a perfect example.

By my understanding of the report, the committee has indicated that it does not feel we have a thorough understanding of how pesticides might effect children differently than adults and how children's exposure to pesticides differs from that of adults.

The committee was asked to examine what is known about exposures to pesticide residues in the diets of infants and children, the adequacy of current risk assessment methods and policies, and toxicological issues of greatest concern.

The committee's examination was complex, and for some, provided all the answers. For some, all the wrong answers. But for most of us, this study resulted largely in still more questions. This is not a criticism, it is the nature of science. Our witnesses today can help shed some more light on these questions.

We will also hear about risk assessment, a relatively new and rapidly developing science. The National Academy of Sciences have defined risk assessment as the process by which scientific data are analyzed to describe the form, dimension, and characteristics of risk or the likelihood of harm to humans.

We should avoid placing undo faith in any risk assessment methodology. For instance, a separate National Academy of Sciences study stated that "the MTD bioassay does provide some useful information for hazard identification and risk assessment." At the same time, NAS asserts that "It is neither perfect nor unalterable, and by itself it is insufficient to produce data from which accurate human-health risk assessments can be made."

While scientists are accustomed to the uncertainties and variabilities inherent in the process of risk assessment, policy-makers and taxpayers are not. We must take the time to understand what the science of risk assessment can, and cannot, tell us if it is to play an effective role in the policy process.

Today, we will also hear about a largely forgotten message in this debate: the benefits of pesticide use. Pesticides are an effective tool in the production of this nation's food and fiber, without out doubt the lowest cost, highest quality of any in the world.

That is a message heard and understood in this room, but a message which has failed to reach everyone. With plenty of hysteria and very little science, 60 Minutes' Mike Wallace helped eliminate Alar from the production of apples.

This debate occurred virtually without discussion of Alar's benefits, which were considerable. Apple growers using Alar were able to harvest an entire orchard just once, instead of periodically over six weeks as individual fruits ripened.

Marketers received more uniformly shaped and colored fruit, which had shelf lives extended from the usual six to eight months up to a year. The volume of fruit produced during the first seven years after tree planting could be doubled and by keeping the fruit on the tree, saved as much as 25 percent of the crop per year.

Consumers had a plentiful supply of inexpensive apples all year long, enhancing their ability to have balanced, healthful diets. The recent NAS report recognizes, once again, the contribution of chemical pest controls, stating, "Their application has improved crop yields and has increased the quantity of fresh fruits and vegetables in the diet, thereby contributing to improvements in public health." Yet none of these benefits were included in the public discussions about Alar.

And so I applaud the Chairman's decision to provide a forum for this discussion about the benefits of pesticide use and his willingness to maintain balance in the Subcommittee's review of this important subject.

Ms. LAMBERT. Thank you. And thank you again, Mr. Chairman, for bringing this important issue before our subcommittee. I just have a couple of questions.

In the report that you have submitted—and I know this may be an odd question—but is all of the data used in preparing your report, is that all of your own data and statistics, or do you use a conglomerate of data and statistics from other agencies.

Dr. MATTISON. We collected, in preparing our report, we collected as much data as we could from as many sources as were willing to provide us information. We got information from the Food and Drug Administration, from the Department of Agriculture, from the EPA, from a range of private industry sources, and industry associations.

Ms. LAMBERT. So most of the studies you used were done by other agencies in compiling your report? Correct?

Dr. MATTISON. The data, yes, that is correct.

Ms. LAMBERT. I was extremely concerned in Dr. Seiber's testimony about that only 4 of the 18 foods studied are 4 of the 18 most consumed by children.

Mr. SEIBER. That is correct.

Ms. LAMBERT. If the issue is, obviously, what happens and how these residues affect children, are we not looking in the wrong places for the answer?

Mr. SEIBER. I think that was one of the conclusions of the report, that FDA sampling strategy again is skewed toward certain commodities and not necessarily the ones that are most consumed by kids. And we identified several foods that we felt should be the subject of more frequent sampling such as orange juice and apple products, bananas and things of that type that are high on the consumption list for kids.

So in that regard, yes, I think we do need to redistribute our resources and sampling strategy.

Ms. LAMBERT. I would assume that that type of information is gathered probably on a continual basis. Could we safely say that probably that will occur in the future, that those sampling methods will be corrected?

Mr. SEIBER. Well, one of the nice things about this report is that it took so long that some of the conclusions have already been put in practice. And indeed the Food and Drug Administration has already picked up on that recommendation in our report.

Ms. LAMBERT. Would that be reflective of the fact that many of our eating habits have changed considerably over the years, and especially for children?

Dr. MATTISON. Yes, that is—

Ms. LAMBERT. Are we just slow in catching up on those changes?

Dr. MATTISON. Yes. We recognize that dietary patterns change both as individuals age and overtime for those same age categories. And the regulatory agencies need to also recognize that and be responsive to those changes in their sampling strategies, absolutely.

Mr. SEIBER. And, quite frankly, some of the fruits that weren't available year-round many years ago, of course now are commonplace, from imported produce. So that certainly changed the utilization of foods over the years.

Ms. LAMBERT. Well, that is one that comes to mind for me. My oldest sister has a newborn and lives in California and has decided he should be a vegetarian. And at this point, a good many of those fruits and vegetables come from outside the country in California.

One last question: When you talk about pesticide residue and the areas that are most affected, you mentioned the immune system, the reproductive, and the endocrine. There were four I believe you mentioned. Maybe I just touched on three.

Dr. MATTISON. Central nervous system.

Ms. LAMBERT. Central nervous system. Does the fact that the pesticides perhaps may be fat soluble have anything to do with those areas that they affect, or does that have nothing to do with it at all?

Dr. MATTISON. In our discussions, we focused on those organs and systems that we thought had the greatest potential for lifetime effects if they were damaged in infancy or in childhood. And it was really more from a biological than a chemical—

Ms. LAMBERT. More like a destructive, an initial destructive?

Dr. MATTISON. Kind of an insult that changed or modified the way that any of those systems functioned. We thought that the—

Ms. LAMBERT. In a growth pattern, or more in a long-term sense as far as—

Dr. MATTISON. More in a long-term sense.

Ms. LAMBERT. OK.

Dr. MATTISON. That is, we thought damage to the central nervous system, damage to the reproductive or endocrine systems, damage to the immune system in childhood, even if it went unnoticed at that time, had the greatest potential for lifelong consequences.

Ms. LAMBERT. Thank you very much.

Mr. STENHOLM. Mr. Inslee.

Mr. INSLEE. Thank you, Mr. Chairman. I would like to add my voice to those who thanked you for the tenor and tone of the way you discharged your responsibilities. We appreciated it.

Last week I was in my hometown, I was visiting a low-income clinic. And there was a dentist there I was talking to who was telling me about the real high percentage of his young patients with absolutely terrible oral hygiene problems and rotting teeth due to their nutritional habits. And we were talking about the need for Federal funding for research to find ways to change parental behavior and perhaps some nutritional aspects to solve this problem.

And the thought—this crossed my mind when we were talking about some of these other research demands that we have and programs that we have for health. I think Dr. Seiber and Dr. Mattison described this as perhaps at the lower end of the risk scale, if you will.

I just wonder if you could point us to other directions, if you had to prioritize the first \$10 million or \$100 million of public money for children's health research or programs, are there higher priorities? If so, could you direct them to us?

Mr. SEIBER. I would certainly—that is an excellent point. Nutritional habits of our kids and the parents that buy food for the kids need to be influenced. We have a nice mechanism for making those kind of impacts on society. We have a cooperative Extension Service that is increasingly devoting its time to home economics-type

problems, including nutritional eating habits. So we have a mechanism out there to get the word out. And Extension is active in all the States in improving dietary choices by the population.

Now, I personally can't recommend how that system ought to be tweaked at the present time, but at least it is good to know that we have a system to get information to the consuming public. So you have a good point, but I can't make a specific recommendation.

Dr. REIGART. I certainly would speak to that. We have largely conquered most infectious diseases of childhood, and that leaves really the two most important things that we can do for children today are to improve their environment and improve their nutrition. And fortunately today we are talking about ways to do both of those. And I think it is almost not fair to say, what would you do with the first \$100 million because you probably would put a piece of it in both areas, in improving their environment and improving their nutrition.

Third, that is sort of a corollary to the way I started, is we certainly need to improve their immunizations. Because immunizations are one of the major ways that we have eradicated serious infectious diseases.

So the three areas of most concern to me for improving the health of children today would be improved nutrition, improved immunization, and improved environments in general. And, of course, pesticides are only a small part of the environment of children.

Dr. MATTISON. I agree with the two previous comments and have no additional.

Mr. INSLEE. Thank you, Mr. Chairman.

Mr. STENHOLM. Mr. Volkmer.

Mr. VOLKMER. Yes. Do we, within the past 5 or 10 years or so, have any of what I call "outbreaks" or problems with infants and children anyplace in this country as a result of pesticide residues?

Mr. SEIBER. Mr. Congressman, the only large case that we have had that affected both children and adults was an illegal use of aldicarb in watermelons and many thousands of people were made ill. None died, fortunately, from consuming melons in that case. From the legal use of pesticides I am not aware of any problems that have occurred.

Mr. VOLKMER. The next question that I have is that the council's report as I understand it has a provision in there recommending that tolerances be based on health factors, not on enforcement factors. Is that correct?

Dr. MATTISON. Sir, the committee was asked to explore the methods used for characterizing risks to infants and children. And in responding to that charge, our deliberations suggested that greater attention needs to be given to the potential health impacts of pesticide residues.

Mr. VOLKMER. Shouldn't we first, before we reduce the tolerance, determine whether or not the tolerance that presently exists is a health hazard?

Dr. MATTISON. In attempting to explore that issue, we looked for data on exposure. And as we have indicated, exposures to infants and children are somewhat difficult to quantitate. And so that is why that is high on our list of recommendations, that is near the top of our priorities.

Mr. VOLKMER. To characterize the risk event before you do anything?

Dr. MATTISON. To characterize the risk.

Mr. VOLKMER. I can understand that. When we do things, at least I hope when we in the Government do things, we do things more on the scientific basis than just, well, I think it ought to be this way, so let's do it that way. Do you understand what I am saying?

Dr. MATTISON. Yes.

Mr. VOLKMER. Now, I can remember back when something very similar to this but it is not the same, when I was first here in the Congress we had a big thing on the question of carcinogens, back when they were looking at a thing called saccharin because it was supposed to be carcinogenic, et cetera. And we had a big fighting thing over that.

At that time, with some little bit of research that I did myself because I was quite upset what was going on, that was the only thing that we had at that time to sweeten things that diabetics could use, because they couldn't use sugar and we didn't have Equal and those type of things at that time, and I found that supposedly some of our vegetables that we presently eat are potentially carcinogenic, without any residues or anything else. But we have never looked at that, have we?

Dr. MATTISON. The committee did spend a very small amount of time discussing the issue of natural products and the potential health hazards of natural products. There is currently a National Academy of Sciences committee that is looking specifically at testing strategies to characterize natural products.

We recognize that that is something that does need to be factored into the ultimate equation.

Mr. VOLKMER. In the total equation, does it not? I mean why just look at additives that you can add to a fresh fruit or vegetable or anything else that is in your food supply, when the food supply itself may be—may be not bad, but potentially is bad and added to it something wrong, right?

Dr. MATTISON. Yes.

Mr. VOLKMER. And if we are able to test, especially on carcinogens now, to the extent that we are going to be able to test, and if we took the Delaney clause and applied it to natural foods as well as additives, wouldn't we be in a little bit of a bind?

Dr. MATTISON. I have seen these calculations, and yes, you are correct, we would be strapped to put a meal on our plate.

Mr. VOLKMER. That is what I figured. That is the answer I wanted and I think the general public should recognize it and the media has never pointed that out. They always take out after the pesticides, residues and all this other stuff. And the media ought to wake up. They ought to start learning what they are talking about.

And, folks, what we are talking about is if we applied it to our natural foods as well as our additives, you may have some difficulties in eating.

Thank you very much. By the way, I want to join with you, everybody else, and congratulating you on this. I think we need to do some of these things. And I agree that perhaps we need to do it on a step-by-step process. You agree with that?

Dr. MATTISON. Thank you, yes.

Mr. STENHOLM. Are you individually or collectively familiar with USDA's pesticide data program?

Mr. SEIBER. I am a bit familiar with it. That is a program that has resulted in the collection of more samples outside, but in concert, hopefully, with the Food and Drug Administration's ongoing program.

I think that is the AMS program that you are——

Mr. STENHOLM. Yes. In your opinion is this useful, helpful to the topic we are talking about today? Do you have any suggestions as to how it could be made better?

Mr. SEIBER. I think it is helpful in the sense that it adds still more to our capability to understand what is in the food supply. The USDA program, as I understand it, is a pass-through program where they have designated certain States to conduct most of the work. Certainly in California the department of food and agriculture in that State has been very vigorous in implementing a program designed around the USDA funding.

So in that regard I believe it is starting to have an impact but it is fairly new. It is only 2 years old, I believe, 2 or 3, so it has not really played out yet.

Mr. STENHOLM. Yes, we have the first compilation of data, the first 6 months of 1992. The entire year of 1992 will be available this fall for us.

And in the first 6 months, it found that of the 2,859 samples, 19 samples were found to be violative, 6 of which were imported, but a relatively small amount of sampling was showing that we have violative problems with pesticide residues on food.

It certainly would be my opinion that this data base is the kind of helpful information that we are going to have to have in order to answer the questions that we are talking about need to be answered here this morning.

Dr. MATTISON. Mr. Chairman, the committee didn't look specifically at proposed modifications of or changes in the way that the regulatory or enforcement structure that was put into place. And in fact in a sense the kind of questions that the committee focused its attention on were data gathering that was probably—could be considered to be outside of the regulatory framework in the sense of violations in terms of exposures.

We are interested in broader definitions of exposures than are characterized by a strategy which looks for violations.

Mr. SEIBER. Mr. Chairman, I would like to just add that there are several department-sponsored initiatives. The IR-4 minor use program and pesticide impact assessment program, both of which have helped tremendously, certainly at the State level, in understanding what is going on with such pesticide issues as residues in foods and human exposure in the case of the impact assessment program. So these have been very helpful.

Mr. STENHOLM. Now, Mr. Volkmer got into this just a moment ago and I want to pursue it just a little further. Is there anything in the findings of this report that provide any insights into the Delaney clause?

For example, there is already at least a hundredfold safety or uncertainty factor built into the current system of determining what

is safe in dietary exposure to noncarcinogens. You have now suggested in your report that an additional factor of up to 10 be applied.

Is there anything magic or scientific about any number included as an additional safety factor, or is it basically just guesswork today?

Dr. MATTISON. We focused our attention in that discussion on noncancer endpoints. We didn't specifically discuss the benefit or harm from the Delaney paradox as it is currently enforced in the United States.

And the reason for the potential three—up to tenfold safety factor is for three particular areas, actually come from analysis of the data. This one tenfold safety factor is typically used for extrapolation across species, one for variation within species, and then when we look specifically at the differences in sensitivity between children, infants, and adults, we observed that there were generally within two to three or fourfold differences, sometimes more sensitive, sometimes less.

It was very seldom that we observed there was as much as a tenfold difference between children, infants, and adults. And so we believe that within that structure for noncancer endpoints, there is an adequate margin of safety.

Mr. VOLKMER. Would the chairman yield just very briefly on that?

Mr. STENHOLM. Be happy to yield.

Mr. VOLKMER. When I listen and try to put it the way I understand things, you are telling me metabolism among infants, depending on individuals, et cetera, perhaps ethnicity and everything else, is a little different in—

Dr. MATTISON. Yes. As children grow and develop, the way that they handle chemicals and the way that they respond to them is different from the way that adults handle and respond.

Mr. VOLKMER. What about within children, isn't that different also?

Dr. MATTISON. There are some differences. That is not an area that I have expertise in.

Dr. REIGART. Actually, the differences between children are less than the differences between children and adults.

Mr. VOLKMER. Thank you, very much.

Mr. STENHOLM. Any other questions?

Mr. Sarpalius.

Mr. SARPALIUS. Did the committee address at all food that is imported into this country that might have been sprayed with any chemicals?

Mr. SEIBER. The committee did have access to data on both imported and domestic food. And at least in the reports that we had, we did not see any major difference between the number of violative residues or the types of residue averages that were generated on residue contents in those two categories.

What we did not look at were specialty foods that may not be included in the general diet represented by mainstream items from Mexico, Chile, et cetera. For the specialty items that might have come in an ethnic food preparation, we did not have data specifically on that point.

Mr. SARPALIUS. This is probably stretching a little bit, but that is one of the concerns of the NAFTA agreement, is what assurances do the American consumers have that chemicals that are outlawed in this country that may be legal in Mexico, that they will be continually using those chemicals and importing basically vegetables into this country.

And I am curious if in your own personal opinion, do you think we do an efficient enough job in monitoring or inspecting vegetables and fruits that come into this country?

Dr. REIGART. I can specifically say that the American Academy of Pediatrics has supported the so-called circle of poison legislation and we feel that there is some risk in the use of chemicals that are not used in this country being imported back in foods.

So the academy's position has been that we do need more control over the misuse of chemicals in other countries.

Mr. SEIBER. My own opinion is that we have two mechanisms. One is the border inspection where we take the samples of produce. That is a fairly good deterrent because no importer wants to have an entire lot seized and condemned for violative residue. So that is strong incentive for them not to import those foods with potentially violative residues.

The second thing is that the United States has inspectors that actually go out into some of the countries of origin and see what is being used. So we have pretty much up-to-date information on what is used. That doesn't mean it couldn't slip through, but at least we have two safety nets.

Mr. SARPALIUS. But one of the concerns is that those inspectors may only inspect 1 out of every 20 trucks that come in. And there is concern about should—is it a problem? Is there a lot of vegetables coming in that have been sprayed, or is this an area that we ought to improve on?

And as we look at food safety, I am just curious if that is something that we ought to be addressing.

Mr. SEIBER. Well, roughly half of the samples that FDA, and I believe this is true also with the State of California, analyzes imported foods from across the border. So there is a reasonable effort going in, certainly in comparison with what is done domestically. Whether it is enough or not, I can't really say.

Dr. REIGART. I am of the view personally from what I have seen that there is more variation in use outside this country than there is within this country, and therefore you need more sampling of foods coming in to properly characterize the risk.

And it is my own belief that we do need better protection from use of chemicals outside this country on foods that then return for consumption in this country.

Mr. VOLKMER. Will the gentleman yield?

Mr. SARPALIUS. Sure.

Mr. VOLKMER. I don't want to get into a big discussion on it, but Dr. Reigart, you mentioned the circle of poison legislation. That legislation would also prohibit the manufacture and use of herbicides in other countries for food consumed in those other countries, even though they have been approved by that country. Do you realize that?

Dr. REIGART. I am fully aware of that. And as I say, I am expressing the view of the American Academy of Pediatrics which has reviewed the legislation and supported it over several years.

Mr. SARPALIUS. Thank you.

Mr. STENHOLM. Mr. Smith.

Mr. SMITH of Oregon. Thank you, Mr. Chairman.

I just have one final question. As you might be able to determine from our questions, we are swirling around this Delaney clause issue, which by the way this subcommittee does not have jurisdiction over.

However, it is of intense importance to us. Dr. Mattison, you called it a paradox. Obviously it certainly is, with the old notion on the 1 part per 1 million and the court finding that there would be absolutely no carcinogen allowed, which might eliminate the possibility of growing raw food. Changes in the Delaney clause, I assume, you would support; is that correct?

Dr. MATTISON. The committee didn't address it specifically. I have my own personal view of the issue.

Mr. SMITH of Oregon. I would like your own opinion.

Dr. MATTISON. When that law was enacted, our understanding of exposures and mechanisms of cancer caused by chemicals was substantially different than it is now.

And I believe that a framework for risk assessment and protection of the population's health needs to be put in place which is responsive to changing understanding of hazards to human health.

Mr. SMITH of Oregon. How do you do that? How would you recommend doing that?

Dr. MATTISON. I would recommend that, and again, this is separate from the recommendations made by the committee in their deliberation, that a biological basis for the mechanism of cancer cause be included in the way that cancer causing agents are regulated. And that differences between those that alter the structure and function of DNA from those that act by different mechanisms be allowed to influence the way that regulatory strategies were addressed to that particular chemical.

That is to say, make the regulation biologically based.

Mr. SMITH of Oregon. Would you do that within the framework of existing political organizations, or would you make this an advisory sort of thing?

Dr. MATTISON. That is a very interesting question. As you may recall from the 1983 report—

Mr. SMITH of Oregon. Whom do you trust, Dr. Mattison? Please, I am sorry.

Dr. MATTISON. I was actually trying to remain silent on that particular question.

Mr. SMITH of Oregon. Yes, I don't blame you. Dr. Seiber, do you have a comment on this question?

Mr. SEIBER. All I can add to the discussion is that I believe that a review and overhaul is badly needed, but I don't have an opinion on how this should be accomplished.

Mr. SMITH of Oregon. Dr. Reigart.

Dr. REIGART. Well, it certainly is my personal opinion only, because the academy doesn't have a position on it. But first I feel like the endpoint of carcinogenesis has been overemphasized in dealing

with environmental hazards, that there are many other risks that were pointed out in this study, particularly the development of children.

And I agree that the Delaney regulation clause needs an overhaul.

Mr. SMITH of Oregon. I thank you all.

Mr. STENHOLM. Any other questions?

If not, we thank you very much for your attendance, your testimony today, and we look forward to your continued work with this subcommittee. I would announce for you and for others at this time, that it is the Chair's intention to hold one additional hearing specifically on H.R. 1627, the Lehman-Bliley-Rowland bill, which is under this subcommittee's jurisdiction.

We hope to do this on or about August 1, and immediately go from that hearing into a markup of this subcommittee concerning the legislation before us. So each of you within your own field of expertise, both personally as well as the wisdom that you have as a result of the study in question today, we would sincerely ask you to look at that particular legislation to make what amendments and improvements to that legislation that you may feel willing and able to give this subcommittee.

And I say this for the benefit of the entire audience here this morning also. And thank you for being here.

Call the second panel, Dr. Graham, Dr. Winter, and Mr. Gianessi.

First witness, Dr. John D. Graham, director, center for risk analysis, Harvard University School of Public Health, Cambridge, Massachusetts.

Dr. Graham, welcome.

STATEMENT OF JOHN D. GRAHAM, DIRECTOR, CENTER FOR RISK ANALYSIS, HARVARD UNIVERSITY SCHOOL OF PUBLIC HEALTH

Mr. GRAHAM. Thank you, Mr. Chairman. I appreciate the opportunity to testify today on the crucial role of risk-benefit analyses in the regulation of pesticide products.

Before beginning, let me acknowledge my center colleagues, Nancy Beaulieu, George Gray, Cynthia Lopez and March Sadowitz, for their help in preparing this testimony.

I have two major points today. Point 1, the National Academy of Sciences has made several sound recommendations for improving the technical quality of pesticide risk assessments, particularly concerning the welfare of infants and children. These recommendations should be implemented by Federal agencies as soon as possible.

Second, while recent public attention has focused on the potential risk of pesticide residues on food, we should not ignore the benefits of pesticides. In fact, there is an urgent need for better scientific and public understanding of the potential benefits of using pesticides in various agricultural, commercial, and residential contexts.

Please allow me to elaborate briefly on these two points. First, the National Academy of Sciences report contains several constructive scientific recommendations. More and better quality exposure

information is needed. Better understanding of the biological susceptibilities of children and young adults is also needed.

As such information is obtained, it will become feasible for agencies such as the Environmental Protection Agency to introduce more rigorous methods of risk assessment into the regulatory process. At the Harvard Center for Risk Analysis, we are enthusiastic about the promise of new distributional methods of risk assessment, such as those recommended in the academy report.

We believe they will employ regulators with more accurate and complete indications of the potential risks of human exposure to pesticides. We have already begun to demonstrate their feasibility through application to specific chemicals. The NAS report emphasizes the need for analysis of variability in human exposures and biological susceptibilities to pesticides.

We also believe that distributional methods should be used to express how confident scientists are in the reported estimates of risk. This kind of uncertainty analysis will help inform regulators and the public of the limitations of the available science and the most promising directions for future research.

My second and more important point today is that, as a nation highly concerned with the safety of our food supply, we should not neglect the potential benefits of pesticide products. Some recent media stories have suggested, for example, that pesticides should be regulated only to protect the health of infants and children, without taking into account the benefits of pesticide use.

This policy stance is not as protective to public health as it may seem at first blush. If we were to ignore the benefits of pesticides and set tolerance levels to assure the maximum degree of protection for the public, we would be logically compelled to set zero tolerance levels in many cases. This would be necessary because there is no scientific test and no group of scientists, not even my former employer, the National Academy of Sciences, that can identify with certainty a nonzero level of chemical exposure that is completely safe.

All exposures to chemicals, whether man-made or natural, carry some degree of risk, and we should not delude ourselves into thinking that our children can be made completely safe. Like all complex technologies in daily life, the responsible application of pesticides will inevitably present some risks that can only be justified by an informed, explicit, and accountable assessment of their benefits.

Were the benefits of pesticides to be ignored in the setting of tolerance levels, there is a real danger that the resulting legal conditions of pesticide use would be unduly stringent, such as would result from the more strict interpretations of the Delaney clause that we were just discussing. Although the benefits of pesticide use are not as well studied and understood as they should be, it is important to consider what might happen if the use of pesticides were terminated abruptly through stringent tolerance levels.

If farmers are suddenly unable to use pesticides, their crop yields per acre might decline due to insufficient pest control. Since the costs of producing the same level of output would then be higher, farmers would be forced to charge higher prices for the crops they produce. A recent study, published in the journal *Science*, indicated

that the food price impacts of bans on pesticides could be quite substantial.

I am submitting this study—attached to my prepared statement—for the hearing record. The benefits of lower food prices have been mentioned in this hearing and I want to emphasize that they are not simply financial. The impact of food prices affects the health of parents and their children. For example, if higher prices for fruits and vegetables cause dietary habits to shift away from these foods, an increase in the risk of cancer, heart disease, and other diet-related diseases can be expected.

This outcome is more likely among low-income populations, where sensitivity to price increases is highest and where knowledge of the health effects of poor nutrition may be lower. In some situations, the loss of a pesticide may cause direct harm to public health as a result of consumer exposure to the fungi that may thrive without the pesticide.

For example, although many fungicides have been shown to cause cancer in animals at high doses, some of the toxins produced by fungi, such as aflatoxin, are also known to cause cancer. One of the benefits of pesticides is the human health protection resulting from destruction of fungi. Even if farmers were to substitute new pesticide products for the products that are banned or restricted, the new products should be evaluated with care.

Many new products are quite promising, but others are not as good as expected. For example, some replacement pesticide products have proven to be more acutely toxic to farmers and applicators, even though they do not leave significant residues on foods. The safety of farmers and farmworkers needs to be carefully considered.

Moreover, the next best alternative to using some carcinogenic pesticides is to use products that may not be carcinogenic, but cause reproductive and neurobehavioral effects in animals at high doses. Tolerances need to be set with the comparative risks of substitutes in mind. When considering tolerance levels for a new pesticide product, we should strive to minimize overall human and ecological risk per unit of crop production, compared to the next best alternative product, even if the risks from the new product's food residues are relatively high.

In the long run, it will be possible to reduce considerably the use of some traditional pesticides through alternative farming methods such as integrated pest management, use of biotechnology products, and organic farming. The promise of alternative agricultural methods deserve serious consideration, both in the marketplace and in the development of public policies.

There is no question, however, that an abrupt termination of chemically intensive agriculture, could not be replaced by these alternative methods without adverse price impacts and dislocations. In the final analysis, our objectives in pesticide regulation are more complicated than simply setting tolerance levels to provide maximum protection to infants and children.

We need to consider the impacts of tolerance levels on consumer health, on food prices, on farmer safety, and on the welfare of low-income populations. A risk-benefit framework will show that some

pesticides should have stricter tolerance levels or should be banned entirely. Others should be used more widely.

The same kind of risk-benefit framework can also be used to inform appropriate transitions to alternative methods of agricultural production. One can criticize the risk-benefit framework on the grounds that it asks regulators to make complex judgments based on a variety of considerations. That is certainly true.

Despite its imperfections, a risk-benefit framework is the best tool we currently have to accomplish this challenging task of regulating pesticide use.

Thank you very much for the opportunity to testify and I would be happy to answer questions once the other witnesses have had a chance to speak.

[The prepared statement of Mr. Graham appears at the conclusion of the hearing.]

Mr. STENHOLM. Thank you.

Mr. Winter.

STATEMENT OF CARL K. WINTER, EXTENSION FOOD TOXICOLOGIST, UNIVERSITY OF CALIFORNIA-DAVIS

Mr. WINTER. Thank you, Mr. Chairman and subcommittee members. I am Dr. Carl Winter and I am a food toxicologist on the faculty of the department of food science and technology at the University of California at Davis.

I am also the director of the university's foodsafe program, which was established in 1992 to facilitate the development and sharing of research-based information. The program receives no funding from the agricultural, chemical, or food industries, or from Government agencies.

The views expressed today are my own and do not represent an official position of the University of California-Davis. I wish to focus my comments on the recent National Research Council report on pesticides in the diets of infants and children. In general, I was quite pleased with the report. There is no doubt that the scientific basis for the assessment of dietary risks from pesticides, particularly with respect to infants and children, can be significantly improved.

The recommendations in the report provide a blueprint from which improvements may be incorporated into the risk assessment and regulatory processes. I do take issue, however, with the recommendation in the report that the EPA modify its decisionmaking process for setting tolerances so that the tolerances are based more on health considerations than on agricultural practices.

While this recommendation may seem quite reasonable, closer examination leads me to conclude that this recommendation is inappropriate. The process of establishing pesticide tolerances is enormously complex and is the subject of a paper I published in Regulatory Toxicology and Pharmacology in 1992 examining the relevance of tolerances as safety standards. A copy of the paper has been submitted for the record.

A major conclusion of the paper was that food safety proposals aiming to reduce tolerances on the basis of health could result in little benefit to public health but may lead to unwarranted restrictions on domestic and international agricultural practices. This

conclusion results from the fact that pesticide tolerances serve important roles as enforcement tools to determine if pesticide applications have been made in accordance with regulations and should not be confused as indicators of potential health effects.

Asking pesticide tolerances to serve roles as health standards would eliminate their effectiveness as enforcement tools and regulators of international trade. If tolerances are to be set as safety standards, it is likely that the vast majority of tolerance levels would increase, often significantly, rendering the tolerances ineffective as enforcement tools. This is based upon the findings, as are documented in the aforementioned article, that theoretical lifetime exposure to residues of most pesticides at the tolerance levels is well below established health criteria.

In addition, in cases where the tolerances were reduced, growers using pesticides properly could not be assured that residue levels would fall below the tolerances. This presents the possibility for significant legal repercussions.

Finally it could have dramatic effects upon international trade, since food producers importing into the United States are subject to the same tolerances as those producing domestically. Reciprocal reductions in the tolerances in the international community could result, leading to nontariff trade barriers for U.S. exporters.

Effective and efficient pesticide regulatory programs must be based upon sound scientific principles, if unacceptable risks are to be controlled while benefits from pesticide risk are maintained. Consistent with this goal, I offer the following four suggestions. No. 1, pesticide tolerances should remain in effect as enforcement tools and should not serve a dual role as safety standards. If a solid scientific case can be made indicating that the specific uses of a pesticide may pose unacceptable dietary risks, the tolerances for those uses should be denied rather than reduced to health-based levels.

In the course of determination of the acceptability of the risks, risk assessors must be allowed the flexibility to use realistic rather than theoretical data when it is available.

No. 2, health-based standards, which I will call action levels, should be established as companions to the tolerances and should represent pesticide- and commodity-specific residue levels of toxicological concern. Determination of appropriate action levels is a complicated process. Factors to consider include the likely contribution of residues of a specific pesticide from other commodities and contributions of other pesticides that produce similar toxicological effects.

The differentiation of short-term and long-term risks and of cancerous and noncancerous effects should be considered as well.

No. 3, once action levels have been established, they can be used to help prioritize pesticide and commodity combinations of greatest health concern. This, in turn, could guide regulatory monitoring programs to make such programs more relevant to health. Currently, monitoring programs are designed primarily to enforce tolerances.

Since tolerances are not health-based and since illegal residues rarely constitute unsafe residues, existing monitoring programs are of little value in consumer protection.

No 4, as a scientist, I am favorably impressed with the recent NRC report and commend the NRC committee for fairly and responsibly identifying weaknesses in our present system of risk assessment and pesticide residue regulation. The recommendations made in the report to improve risk assessment methods are innovative and based on sound, solid science.

It should be pointed out, however, that implementation of the committee's recommendations will require significant expense, since the committee recommends major changes in the procedures from which food consumption and pesticide residue data are obtained, toxicological studies are performed, and risks are estimated.

Just as it is critical that the benefits of pesticide use be weighed against the risks, we must also consider whether adoption of the NRC committee's recommendations will provide an appropriate increase in consumer protection. Considerable scientific debate exists as to the actual health risks from pesticides, since risk assessment is such an imprecise science and since appropriate data for use in risk assessment are often not available. From an overall perspective, however, few would argue that the risks from pesticides in the diet are of significant concern when compared with the risks of microbiological food contamination, malnutrition, and even naturally occurring toxins.

With respect to pesticide issues, most agree that worker risks and environmental effects are of much greater concern than food residues. While improvements in dietary pesticide risk assessment and regulatory practices are welcomed by the scientific community, I believe that society would be better served if resources were directed toward programs investigating ways to reduce the use of agricultural pesticides rather than toward ambitious dietary pesticide risk assessment and regulatory programs.

Thank you for providing me the opportunity to share these views. [The prepared statement of Mr. Winter appears at the conclusion of the hearing:]

Mr. STENHOLM. Thank you.

Next we will hear from Mr. Leonard Gianessi.

STATEMENT OF LEONARD P. GIANESSI, FELLOW, RESOURCES FOR THE FUTURE

Mr. GIANESSI. Thank you, Mr. Chairman. My name is Leonard Gianessi. I am a fellow at Resources for the Future a private non-profit research organization here in Washington, DC. My statement is my own and does not represent the views of RFF.

I have worked for the past 7 years collecting information on the uses and amounts of pesticides used in U.S. agriculture. I have worked closely with plant pathologists, entomologists, and weed scientists across the country to assemble this information.

Today I will briefly describe and summarize what I have learned about why U.S. farmers make extensive use of synthetic chemical pesticides. Crop yields would decline in this country if farmers did not use synthetic chemical pesticides because nonchemical alternatives are either nonexistent or less effective in the control of pests.

For example, it has been estimated by U.S. weed scientists that for the Nation as a whole, for field crops such as field corn and cot-

ton, that yields would decline 20 to 30 percent if American farmers stopped using synthetic herbicides for weed control.

The major alternative for weed control in these types of crops is cultivation of the weeds with tractors. While cultivation can be used, and is extensively used, to cultivate the weeds out from between the rows of corn and cotton plants, it is very difficult to use cultivators to cultivate weeds out from within the rows of plants, the weeds that are growing at the base of the plants.

So herbicides are currently used to control those types of weeds. But if synthetic herbicides weren't used to control weeds within the rows of those plants, it has been estimated, that nationally, we would lose 20 to 30 percent of our yields in corn, cotton, and other field crops.

Other national level yield loss estimates that have been made by our crop protection scientists include: Reductions in rice yields of 53 percent without synthetic herbicides; reductions in apple yields of 40 percent without synthetic fungicides; and reductions in peanut yields of 66 percent if there were no synthetic insecticides or fungicides.

These national yield loss estimates are built up from State-by-State estimates that scientists have provided. And let me just state that for certain regions of the country the impacts would be greater, particularly in southeastern States, such as Georgia, Alabama, and Florida, with hot, humid summers, with mild winters.

Pests such as insects, diseases, and weeds proliferate. In the Southeast in crops such as cotton and peanuts, the crop protection scientists have estimated that without synthetic chemicals, growers would lose about 80 percent of their yields.

Now, in addition, crop production costs would increase if U.S. farmers cease using synthetic chemicals, because many of the nonsynthetic chemical alternatives are significantly more expensive than the synthetic chemicals.

For weed control many growers of high value crops such as tomatoes, can use hand labor to pull weeds or plastic mulch to smother weeds and not have to use synthetic herbicides. However, the use of hand labor or the use of sheets of plastic to smother weeds costs growers approximately \$300 per acre, while the synthetic herbicides cost growers of fruit and vegetable crops \$15 to \$20 per acre.

Many organic growers do use these kind of methods in the production of vegetable crops and it is one reason why organic food is often more expensive than the food produced with synthetic pesticides.

Many organic growers also use pesticides as well. Organic growers can't use synthetic chemical pesticides but organic growers can use natural substances that kill pests. For example, many organic growers use sulfur compounds and copper compounds to control diseases of their crops. Generally, organically approved alternatives for insect and disease control are less effective in controlling pests than are the synthetic chemicals.

Thus, to achieve adequate and equal control, the nonchemical alternatives often have to be used much more frequently by the organic growers and at a higher cost. For example, in northeastern apple orchards, the cost of pesticides for an organic apple orchard is about \$250 an acre. They are buying sulfur and various natural

insect killers. But for standard conventionally grown apples with synthetic chemicals, the cost of pesticides is \$95 an acre.

The conventional apple grower is estimated to spray about 26 pounds of synthetic chemicals while the organic grower uses about 100 pounds per acre of natural pesticides. So organic growers have to use pesticides, too. They just don't work as well and they cost more. They also carry certain kinds of risks.

However, sulfur and copper and these types of natural products only control certain diseases, and in particular, only certain diseases of apples. Apple diseases not controlled by sulfur and copper include rots such as bitter rot, white rot, and black rot. Again, if apple growers stopped using synthetic chemicals, these rots would probably infect and occur in about 25 to 50 percent of the apples grown in orchards in mid-Atlantic and southeastern States.

Again, these States would be hard hit because of their mild winters and their high rainfall and high humidity. Currently those rots are controlled quite adequately to levels below 1 percent incidence with the use of synthetic chemicals. So farmers select synthetic chemicals to control pests because alternatives are either nonexistent, cost more, or they work less well in preventing damage due to pests.

The NAS report, "Pesticides in the Diets of Infants and Children," does include several case studies of the risks of specific pesticide active ingredients. I will briefly describe some of the benefits of the products that are described in the NAS record report. Aldicarb was one of the pesticide active ingredients described in the NAS report. They did a case study of aldicarb use on potatoes and pointed out correctly that aldicarb has not been available for potato growers to use since 1990 when it was voluntarily withdrawn from use.

Potato growers are currently petitioning EPA to restore potatoes to the aldicarb label. Without aldicarb what the potato growers have found is that alternative chemicals have to be used five or six times per acre to control the same pests that were controlled with one application of aldicarb.

Thus what potato growers are telling EPA is that the loss of aldicarb has actually increased the spraying of pesticides in potato fields. So one of the benefits, if you will, if you think about the aldicarb situation, is that it fit in real well with this notion of reducing pesticide use, particularly in potatoes. Without the single application of aldicarb, growers are applying five, six, and seven, as many as eight sprays as substitutes.

Benomyl was one of the pesticides included in the academy's report. Rice growers face the potential loss of benomyl because of a strict interpretation of the Delaney clause.

So rice growers have recently commented to EPA on the uses of benomyl in rice production, particularly in southeastern States, again States such as Mississippi, Louisiana, and Texas. They report that benomyl is the only synthetic fungicide that is available to control the disease known as rice blast. Epidemics of rice blast occurred in southeastern States in both 1991 and 1992.

The use of benomyl has been estimated to have saved rough rice valued at approximately \$85 million for each of 1991 and 1992.

Again, the product is the only synthetic fungicide that works to control that particular disease.

That concludes my summary statement. Basically it is my conclusion that farmers have sound, rational reasons for using pesticides, whether they are conventional growers using synthetic compounds or organic growers using natural pest killers.

These pesticides are targeted against pests that would significantly lower the quality and the quantity of food production in this country.

[The prepared statement of Mr. Gianessi appears at the conclusion of the hearing.]

Mr. STENHOLM. Mr. Smith.

Mr. SMITH of Oregon. Thank you, Mr. Chairman.

Dr. Graham, based upon your testimony, am I correct in assuming that you would not support the replacement of Delaney with a statutory 1 in 1 million standard?

Mr. GRAHAM. If the 1 in 1 million standard were to be enforced without regard to what the benefits of pesticides are, I certainly could not support that.

Mr. SMITH of Oregon. Then are you one among those scientists who believe, as I think did the National Academy of Sciences, commenting on MTD, that MTD was an unreliable measurement?

Mr. GRAHAM. A lot of what I know about the MTD issue I read in that report by the National Academy of Sciences. And it is an interesting report to read. I mean that report conveys a lot of tension, legitimate intellectual tension between scientists.

I don't think there is a strong consensus in the toxicological community on the MTD issue and I think that report fairly conveys that.

Mr. SMITH of Oregon. Yes, I believe it does, too. So we get to the point that risk assessment is very difficult. Evidently the science portion of our society has failed and the legislative side has failed with Delaney.

I am going to ask you the same question that I asked Dr. Mattison. Where does the public, the decisionmakers, and this Congress, go to find a method by which we can properly assess risks in society?

Mr. GRAHAM. I think we should go back to Dr. Mattison's answer to that question, which I thought was a very good answer. What he commented was first of all that the Delaney clause of 1958 was written at a time when we didn't know nearly as much as we do today about mechanisms of cancer, of have the ability to detect minute concentrations of residues.

So that wasn't necessarily bad science in 1958, but it was the best science we had. We have a lot better science today and I think that you could get a broad consensus in the scientific community that we should have a rewrite of the Delaney clause.

Now, how we should move to a more difficult question. My own preference would be in addition to the kind of change that Dr. Mattison wrote, would be simply to write some kind of law that treated a pesticide residue on raw foods and on processed foods, all of them in some form of a risk benefit kind of framework.

And so that would move it more in the direction of something like what we have now in FIFRA, but possibly with a more explicit

guidance to the agencies on what kinds of human health considerations to give emphasis to. So I would like to see certainly some kind of risk benefit test rather than Delaney.

Mr. SMITH of Oregon. Would you support 2 parts per 1 million?

Mr. GRAHAM. I would support zero, if we could do zero, wonderful. But I think unfortunately that is not practical.

Mr. SMITH of Oregon. That is what we have now is zero, basically, as the court has interpreted Delaney, I think that is true. Obviously that is not beneficial to this society. And our problem is how do we advance the fact that we need to increase a chance of cancer, change Delaney?

Mr. GRAHAM. Well, let me elaborate on this a little bit. One of the temptations of my colleagues in the natural and biomedical sciences is to believe that if we just studied this problem hard enough and put more money into the science of this problem, we ultimately could identify that precise level of residue in foods that is safe.

And then once we identified that number, we might add a margin of safety and then set that as a tolerance level. One thing I think the subcommittee should be aware of is that there are inherent limitations to what science is going to be able to tell us about that exact level.

And as a result, pesticide residues on foods are always going to pose some element of risk, just like every modern technology does that we use in our life. The only real justification for leaving any residues of pesticides on foods is that we think that there is some benefit to using those pesticides. There is no other intellectual, logical justification for using those pesticides.

And that leads me to the conclusion that whatever the rewrite of Delaney or FIFRA would say, it would have to have in there some consideration of both the risk and the benefit.

Mr. SMITH of Oregon. And just a final quick follow-up. In your opinion, a risk method of 1 to 10, how much could the public be protected by proper cooking and proper preparation of food, particularly fruits and vegetables?

Mr. GRAHAM. I think I better pass on that one. I will let my colleagues take a crack at that. Anybody? You might have something to say on that one.

Mr. SMITH of Oregon. Well, pick five and that will get you right in the middle.

Mr. WINTER. Your question relates to the myriad of different food safety risks in addition to pesticides or specifically what a consumer can do to minimize their pesticide risks on the basis of—

Mr. SMITH of Oregon. Yes, what can a consumer—how important do you think is the question of the preparation of food and the handling of food, particularly fruits and vegetables, to the reduction of risk?

Mr. WINTER. I think it is very appropriate, particularly when we talk about the reduction of microbiological risks, which are our No. 1 food safety priority. Washing and cooking foods may do a wonderful job in eliminating the bacteria, fungi, algae, and the types of organisms that have been shown to have documented human health effects.

With respect to pesticide residues, once you get to that stage, the evidence suggests that the residues are very low and you may be able to reduce them even more through these processes. I think the overall balance of food safety indicates that the greatest benefit is going to be from the microbiological end.

Mr. SMITH of Oregon. Thank you.

Mr. STENHOLM. Mr. Inslee.

Mr. INSLEE. Thank you, Mr. Chairman.

Dr. Graham, I was intrigued by some of your comments about the 1 in 1 million. Could you elaborate on why in your opinion that would not be a prudent policy, taking in consideration the alternate risks and benefits?

Mr. GRAHAM. Well, the first thing we should do for a moment, we should reflect upon what that number means, 1 in 1 million say of contracting cancer on a lifetime basis. And let's suppose for a minute the way we calculated those risks were absolutely correct.

Assume there is no uncertainty in that, so we are dealing with a correct probability. To give you a sense of perspective, there is a chance as we walk out of this hearing room that an airplane, flying say from Boston to National Airport, will miss the National Airport and strike and kill us on the ground. An involuntary risk, but a tiny risk that we all do in fact face.

You can do actuarial calculations that this risk is equal to about 5 in 1 million for a baby born today. Therefore, when you talk about a risk level of 1 in 1 million, that is a very minute risk. I might note that no one argues that we should have this hearing underground in order to provide that ample margin of protection. No one says we should build all of industry and residential homes underground.

So the number, if you trace the history of it, and I would be happy to share with the subcommittee the history of that number, has only an arbitrary basis. There is no particular reason why we should focus on that particular level of risk.

So to get back to the bottom line of your point, the only reason that we can justify imposing on our parents, our children, or anyone, any level of risk, is because we think as a society there is a compelling reason to do so, some benefit.

My own opinion is that the food price benefits of using pesticides, particularly in the short run, are probably a very compelling justification in health terms, as well as in economic terms for not insisting on some number like 1 in 1 million.

Mr. INSLEE. If I can follow up a little bit, I was reading an article in Science magazine, it was talking about risk analysis and what the public can comprehend and accept in regard to risk.

And one of the points that they made is that one of the areas that increases the public's refusal to accept risk is their lack of knowledge about the risk. In other words, the less you knew about the risk, the less willing you were to accept it.

Do you think in this getting out of the Delaney box that we are in and paradox, is there some way getting out of that to say that we ought to increase people's knowledge about the risk, then let them make their own independent decisions about that?

Is that one of the options we ought to be exploring?

Mr. GRAHAM. Yes, I think any time that you can bring an element of choice into a household's decisionmaking about any form of risk, I think it is a plus. But let me relate your question in a somewhat different fashion.

I'm thinking of the problems with taking a position through our Federal Government that scientists know some particular level of residue in foods that is safe, and there isn't any risk and taking that position with confidence and having the prestige of the National Academy of Sciences all over it, one of the problems with that is as the science progresses, as it did with the Delaney clause, we are going to discover that there may be subpopulations of children or infants that are not even protected by what we just said was the safe level of pesticide residues in foods.

And as a result, we have another unfamiliar risk that people didn't think that they were exposed to. I think that we need some degree of candor, with the public, that any level of chemical residue, man-made or natural, is going to pose some risk or at least could pose some risk.

And as a result, any attempt on purely biomedical grounds to say this level is unsafe and this is safe, I think in the long run that miseducates the public about what they really need to be thinking about, which is the level of risk and what the benefit is.

Mr. INSLEE. Mr. Gianessi, could you help me, I talked to some folks who are attempting to institute integrated pest management to reduce their reliance on pesticides. And when they have done that, they found a need for using smaller spectrum pesticides, that they are safer for a larger number of organisms, if you will, and yet they are finding difficulties getting access to those.

Is that a valid concern of folks who want to go to a more biologically based pest management system?

Mr. GIANESSI. Yes, and it is becoming more of a problem for growers. Many successful operating integrated pest management programs that are currently in existence rely upon selective pesticides, pesticides that will kill the key pest and leave beneficial organisms in an orchard that will then control other pests.

Unfortunately, in the reregistration process that is currently going on, many of these selective pesticides are being voluntarily dropped by manufacturers, their registrations are being lost. And in order to control the key pests in the orchards, growers are forced to resort to broad spectrum alternatives that not only kill the key pests, but all the other beneficial organisms as well.

So we anticipate this as an increasing problem, one that we think the agency should pay attention to: Preservation of pesticides that are important for these integrated programs.

Mr. INSLEE. Thank you.

Thank you, Mr. Chairman.

Mr. STENHOLM. Dr. Graham, this airplane from Boston heading for National—

Mr. GRAHAM. It thought it was.

Mr. STENHOLM. Do the odds increase or decrease after 12:30 p.m. on Wednesday? The answer to that will have a lot of effect on how much longer I question you.

You stated in your testimony that we should not ignore the benefits of pesticides, in fact there is an urgent need for better scientific

and public understanding of the potential benefits of using pesticides.

And that level of public understanding is a frustration that we all have, but it also gets right down to the heart of where this subcommittee is going to go, because as we have said over and over, the consumer is always right regarding the safety, the quality of whatever we are talking about, in this case food. The consumer is right.

The challenge to this subcommittee is to address that part of your question also. And that is increasing the educational level of the consumer as to what the risks are. The three of you have testified very eloquently that there are risk/benefit ratios and pointed out that the elimination of pesticides would not necessarily create a safer food supply.

And yet we have many people that testify before this subcommittee that indicate very strongly that that would be the case. And it is one of the frustrations to me is that you can't prove scientifically one way or the other. There is always going to be a question that can be raised that can be asserted that certain things are going to happen.

I think it is very interesting when you look back at the study that we have talked about to some degree this morning, this hearing was not totally on that subject, but it was the basic framework, the pesticides in the diet of infants and children, the genesis of that study was the Alar in apples scare which it turned out to be nowhere close to what we feared at the time that it came up.

But we have the study and it is amazing to me what was asked of you to do, those of you who conducted the study, and what was not asked. And the perception of the American people and even members of this subcommittee, myself included, the perception is that there was something else that we were looking at.

What we are now talking about is the need of the improved methodology so that we can in fact answer some of these questions. It is literally amazing to me that we only recently started developing data to be used for answering the questions that bring us to the point of the inability of legislating a reauthorization of FIFRA.

And it is not just this data base. As we deal with the Clean Water Act, and I will only speak from a Texas perspective, it is literally amazing how little data we have collected as to what the problem is. We always legislate the solution to the problem without ever really stopping and asking what is the problem.

We are only now beginning, and I think this is a key to the direction that we need to go. We need to start, as this study on infants and children suggests, we need to start asking relevant questions. We need to start finding out if there is a problem by looking at our methodology and seeing if in fact there is a problem.

If it is, then as we stated over and over, then I don't know of a single producer of any agricultural product that would not switch and change immediately, if we are using something that is truly harmful to the health of infants and children.

And as we pointed out earlier, all of us grow up. I mean, you don't stay a child forever. Although having been home to my constituency, some suggest that maybe certain Members of Congress do that from time to time.

Dr. Graham, are there any other examples of risks and the ratios of risks and the perception of what the people believe and what is actually factual, any of your work along those lines, say in alcohol, automobiles, firearms, et cetera?

Mr. GRAHAM. Well, in one of the questions of the previous panel, I was intrigued by the question to the gentleman who was the head of the American Academy of Pediatrics, his name is not right in front of me right now, so I apologize to him, but one of the things I was thinking about as they asked that question was how many children there are riding bicycles in their neighborhoods without, for example, a bicycle helmet.

I think it was instructive to have each member of this subcommittee, I am going to do this just because, as I was thinking about it, listening to the testimony, do a little calculation on what the risk to those children is of not only dying from falling off a bicycle but being seriously injured, and compare that for example to these 1 in 1 million standards that people are advocating with regard to pesticide residues.

I think there is really a big mismatch between what the dangers are that our children face that we know they face, and those that we speculate that they might face if we were to collect enough data to figure it out. And as you can tell from my testimony, I am a little skeptical that if all those NAS recommendations on the science were implemented, 10 years from now we had all that data in, it still may not be clear at all whether children and infants are subjected to risk.

I agree with the recommendations, we should go forward with them, we should gather that information, but we shouldn't delude ourselves into thinking that we are going to find that precise amount of residue that is safe. It is not going to be that easy.

Mr. STENHOLM. Dr. Winter, would you amplify a little more in your testimony where you say pesticide tolerances should remain in effect as enforcement tools?

Mr. WINTER. Certainly.

Mr. STENHOLM. And should not serve as a dual role as a safety standard. Explain what you mean.

Mr. WINTER. Thank you for the question, Mr. Chairman. What is very difficult for many people to understand is the nature of pesticide tolerances themselves. Pesticide tolerances are set as enforcement tools to determine whether an application of the chemical has been made in accordance with the legal directions on that pesticide's label.

They are set in practice to be slightly higher than residue levels that one would expect if the chemical were being used properly. So they are really there to protect a user of a chemical from having a residue in excess of a legal limit if they are using the chemical properly.

And historically this is how tolerances have been established. Now, many people will think that if this is the case, who is minding the store, what is the issue here, what about health criteria? And the health criteria are considered when the determination is made to allow or to not allow that pesticide tolerance.

Since the tolerances are set to be artificially high, the actual risks are typically dependent upon the residues that one would ex-

pect people to be exposed to. And much of our residue data has adequately shown that residues are typically well below the tolerance levels when in fact they are detected.

So we have two different systems in place. Actually we have a tolerance system in place which is an enforcement standard, and then we are talking about making the tolerances health based. We are really talking about apples and oranges here.

And if we are going to be effective in enforcing the label requirements, we need to have a tool such as tolerances in hand. However, that is not going to answer any of the questions about the risks of pesticide residues. That is where we need to have a separate type of standard that is based on health considerations.

Mr. STENHOLM. Mr. Gianessi, do you see any trends, either favorable or unfavorable, regarding the use of pesticides in this country?

Mr. GIANESSI. There are trends in various directions right now. Herbicide use for many of our major field crops in terms of the amounts, pounds on the ground so to speak, are declining.

Newer low rate herbicides have been introduced that are being used at three-hundredths of a pound per acre instead of 3 pounds per acre as some of the older products are used. These are newly registered products at EPA. So for certain of our major field crops such as soybeans, we see very large reductions in total pounds of pesticides used.

In other crops, we do see some application of integrated pest management techniques, particularly in the fruit and vegetable crops, that have stabilized use, after initial reductions.

Several concerns that we do have that I have alluded to is as a result of the loss of some of these products that work well in the integrated systems through the reregistration process and under Delaney, we may see an increase in pesticide use in apple orchards and in vegetable operations, because these selective compounds are being lost. We are observing that. On the other hand, there are certain new crop cultivars that are very high yielding, particularly rice cultivars that have been introduced in the past 10 years. They have helped increase rice yields considerably in this country.

Unfortunately they are very susceptible to the major diseases that attack rice. So in this crop we are seeing an increase in fungicide use because of the change to a new cultivar. American agriculture is enormously complex.

One of your frustrations in dealing with this topic, one of the frustrations of the committee is agriculture's complicated nature. There are individuals that can come from any part of the country and tell a story to support just about any point of view. My recommendation, when I look at the NAS report, being about 400 pages long and exclusively focused on the risks, would be to see a document that was about 400 pages long talking about the complicated nature of the benefits of pesticides in American agriculture.

I think that would go a long way toward some of these concerns of the public and our policymakers.

Mr. STENHOLM. Going back to your bicycle analogy, one of the difficulties we have is that there is a fundamental difference between your and my choosing to ride a bicycle, choosing to put a hel-

met on or choosing not to, and the food supply that we have before us.

There is a fundamental difference to that which we have to try to address. And I will carry your analogy a little further on the bicycle and it really hits home to me because I have a health facility in my district which houses men and women who have been injured in motorcycle accidents and head injuries that occur from it. And it is a tragedy to see it. And yet most of us would understand that the freedom to ride a motorcycle with or without a helmet is my business.

And then when you have an accident like that happen, suddenly it becomes the public's responsibility to care for the individual who has chosen not to exercise their individual responsibility.

And that is where the risk benefit analysis have to be talked about in an intelligent way. They have to be portrayed and understood for what they are, that you cannot accomplish certain goals unequivocally without recognizing that there are benefits to pesticides as well as potential risks to pesticides. It has to be looked at.

I make the same request of each of you as I did the previous panel. We intend to move forward now in the markup of the legislation as we attempt to reauthorize FIFRA, but also hopefully to provide some guideposts for the administrative.

The earlier comment that suggested legislation is not needed in some of these areas more closely resembles my own feeling in a lot of areas, but we want to pursue it because I think most of us admitted that while we have the safest food supply in the world, it can be made safer.

There are legitimate concerns, particularly when we start talking about our children, that need to be looked at and if we can positively and productively address those concerns in this legislation, we certainly want to.

But we would ask of you within your own fields of expertise to take a look at this legislation, to offer what suggestions, comments of things that are in it that perhaps are not going to be as helpful as we would think, as well as parts that are not in it.

And I refer specifically to the legislation, H.R. 1627, Lehman-Bliely-Rowland bill, which has 101 cosponsors, almost a majority of the full Agriculture Committee, a majority of this subcommittee seemingly have decided that that is a direction they want to go, and I think that will serve as a useful markup vehicle from which we can work.

So thank each of you for being here today. We appreciate your input very much into this subject, both today and in the future. No further business to come before the subcommittee today. This hearing stands adjourned.

[Whereupon, at 12:40 p.m., the subcommittee was adjourned, to reconvene, subject to the call of the Chair.]

[Material submitted for inclusion in the record follows:]



TESTIMONY

BEFORE THE

HOUSE OF REPRESENTATIVES

COMMITTEE ON AGRICULTURE

SUBCOMMITTEE ON DEPARTMENT OPERATIONS AND NUTRITION

*THE RISKS AND BENEFITS OF PESTICIDE USE
IN U.S. FOOD PRODUCTION*

Presented by:

J. Routt Reigart, M.D.

July 14, 1993

Mr. Chairman, Members of the Subcommittee. My name is Routt Reigart. I am a professor of pediatrics at the Medical University of South Carolina where I am involved in the practice of general pediatrics and environmental medicine. I am the Chairperson of the Committee on Environmental Health of the American Academy of Pediatrics. Thank you for providing me this opportunity to speak today on the risks and benefits of pesticide use in our nation's food production. I come to speak to you today not as a professor or an expert in environmental health, but as a representative of the 45,000 members of the American Academy of Pediatrics. Most of these members are practicing physicians who care for children and counsel parents on a daily basis. They are familiar with the concepts of risk assessment, but few are experts in performing formal risk assessments. Most know a great deal about infant and childhood nutrition and are comfortable in providing counseling to the parents of their patients regarding appropriate nutritional practices. In this context, they expect experts and specialists in risk assessment to provide to them adequate information about the risks of pesticides and other chemicals in food to allow them to make appropriate recommendations for their patients. They would like to be able to say, without qualification, "your infant or child should eat a diet rich in fruits and vegetables. You need not be concerned about hazards of pesticides in your selection of fruits and vegetables for your child."

In addition, when asked about the hazards of pesticides in food, pediatricians would like to be able to make several additional affirmative statements:

1. "Pesticides used on our food have been tested for safety to infants and children."
2. "The risk assessment process has taken into account the differences in children's diets including diet selection and the higher caloric intake of infants relative to their body mass."
3. "The risk assessment process has taken into account the differences in the way children absorb, metabolize, store, and clear chemicals and other toxins from their bodies."
4. "The use of pesticides is regulated and regulations are enforced to ensure that pesticides are used in a safe and proper fashion."
5. "Foods which are available in the marketplace have been inspected to ensure that they do not contain pesticide residues which exceed approved limits which are based on an appropriate risk assessment process which has taken specifically into account risks to children and infants."

It is self-evident, but cannot be stated too often, that "children are not simply little adults." Attempts to extrapolate the risks of pesticides to infants and children based on adult risk assessment are doomed to fail, due to the many differences between children and adults. Furthermore, for chemicals persistent in the body, or for effects with long incubation periods, the seventy odd years of life expectancy for a child is a very long period at risk.

The American Academy of Pediatrics believes, given the available information on the risks

of pesticides in the diet, that it is prudent to recommend that infants and children be provided a diet rich in fruits and vegetables. No known risk from pesticides presently outweighs the benefits of this healthful diet. The American Academy of Pediatrics also understands the benefits of pesticides to agriculture and accepts the proposition that it is possible to use pesticides in a fashion which is not hazardous to the health of infants and children. It is not possible to use pesticides in such a fashion without knowledge of the actual risks to infants and children. At the present time it is clear that it is not possible to state that pesticides have been evaluated for safety to children and their special needs. The American Academy of Pediatrics supports the development and funding of studies necessary to provide sufficient data to make risk assessment decisions which adequately protect the health of infants and children. The American Academy of Pediatrics supports regulation of the use of pesticides on foods and supports strong enforcement of such regulations. The American Academy of Pediatrics supports a strong program of inspection of foods to ensure that they are free of pesticide hazards.

It is my own view, based on my own experiences, that many families and physicians are very concerned that there is so little information regarding the safety for infants and children of pesticides in our food. Such concern will only be alleviated when the risk assessment and regulatory process clearly evaluates and assesses risks to children of pesticides in their diet. Since children cannot make their own choices in food selection, they are potential unwilling victims of any errors we make in this process. We owe them the highest level of protection possible. They deserve the highest level of protection possible.

Thank you.

DONALD R. MATTISON
Professor of Environmental and Occupational Health
and Obstetrics and Gynecology,
Dean of the Graduate School of Public Health,
University of Pittsburgh

and

Vice-Chair
Committee on Pesticides in the Diets of Infants and Children
National Research Council

Before the
Subcommittee on Department Operations and Nutrition
Committee on Agriculture
United States House of Representatives
July 14, 1993

Mr. Chairman: I am Donald R. Mattison, vice chairman of the National Research Council's Committee on Pesticides in the Diets of Infants and Children. The National Research Council is the operating arm of the National Academies of Sciences and Engineering. I am accompanied by Dr. James N. Seiber from the University of Nevada who is also a member of the committee. We are pleased to be here to discuss our report Pesticides in the Diets of Infants and Children.

As a physician and Dean of a School of Public Health I believe that the subject of this report is of great significance. Speaking on behalf of my colleagues on the committee, I want to stress the importance we placed on the charge we were given, which was to determine the methods used by the regulatory programs of the federal government to protect the nation's infants and children from pesticides in their foods.

I also want to take this opportunity to acknowledge that the preparation of this report would not have been possible without

the efforts of my colleagues on the committee and the staff of the Board on Environmental Studies and Toxicology and Board on Agriculture of the National Research Council, National Academy of Sciences. The 14 members of this committee contributed an enormous amount of time - as volunteers - for what has proved to be an ambitious and complex study.

While pesticide use has increased the quality and quantity of foods in our diet, they are by design toxic to some living organisms. Because they are used in agriculture to control rodents, insects, fungi, nondesirable plants etc. -- pesticide residues are found on foods, and as a result, cause concern for human health. Recognizing the benefit as well as potential for human harm, laws have been enacted to protect human health while allowing the use of pesticides -- as long as the risks to health are not unreasonable. There is concern, however, that as currently enacted these laws may not protect the health of all of the diverse populations of the United States.

Recognizing that the regulatory focus may not be adequate, in 1988 Congress asked the National Academy of Sciences to convene a committee to examine the quality of the science used in characterizing risks to infants and children from the presence of pesticide residues in foods, and the methods used by regulatory agencies to characterize those risks. The testimony presented here summarizes the findings of our report.

The committee began their deliberations with the acknowledgment that children are different from adults and then proceeded to examine if those differences would always result in increased risk. Characterization of risk involves understanding how a toxicant produces adverse effects and defining the exposure to that toxic substance. The topics examined in greatest detail for our analysis of risk assessment methods for infants and children included: sensitivity to pesticide toxicity, the potential for long term harm resulting from toxicity during growth

and development, exposure of infants and children to pesticides in their diets, and methods used to calculate risks for infants and children. After analysis of these topics and extensive deliberations the committee recommends that the federal government:

1. change its scientific and regulatory procedures to specifically address the potential risks to infants and children from pesticide residues in their diets
2. make immediate changes in the data gathered on the food consumption patterns of infants and children and the analysis of those foods for pesticide residues
3. adopt a new method of risk assessment to more accurately characterize risks to infants and children from pesticide residues in their foods and environment
4. develop toxicity testing methods for pesticides which specifically address risks to developing infants and children

In our approach to this request to examine the methods for characterizing risks to infants and children from pesticide residues in foods we utilized the framework for risk assessment which was developed by a previous committee of the National Research Council, National Academy of Sciences, Risk Assessment in the Federal Government. This framework for risk assessment has four steps: hazard identification, hazard characterization, exposure characterization, and risk characterization.

The first step - hazard identification - asks if the chemical of concern has been demonstrated to have adverse health effects in either experimental animals or humans. Note that to protect the health of the public we would prefer to use data from animals and not require the demonstration of human disease from pesticides in our foods.

To complete our analysis of methods and data for this step in the risk assessment process the committee collected and examined the available data on the toxicity testing of pesticides in young and developing animals. Unfortunately, there is little data specifically exploring the toxicological impact of pesticides on developing animals. For that reason the committee also evaluated the comparative toxicity of drugs on developing and mature animals and humans.

The committee found that the changes that accompany growth and development are also accompanied by changes in the way the body handles pesticides or other chemicals. In some cases the potential for toxicity is greater in infants and children and in other cases the potential for toxicity is less. Unfortunately, there is no simple way to predict which compounds will represent greater hazards for infants or children than adults. However, where data is available on the toxicological differences between infants, children and adults the difference is generally between two and four fold - there is rarely as much as a ten fold difference.

The second step - hazard characterization - explores how and where the chemical acts to produce disease or illness. This step is especially important if we want to use toxicological data gathered in experiments conducted in animals to protect human health. While the biology of experimental animals is generally similar to humans - they can differ in critically important ways for toxicology - and these differences are of special concern for developmental toxicology. For example, one fundamental difference between children and adults is the concern that if toxicity occurs it can impair the potential for growth and development and as a result have long term adverse health consequences.

As indicated above, the committee noted that there were often quantitative differences between infants, children and adults. However, there were few qualitative differences between developing

animals and mature animals. While children and adults may differ in the sensitivity of their responses to a pesticide or drug it was unusual for them to differ in the way they respond to the chemical. This suggests that information on where a chemical works and how it produces toxicity in the adult may be useful in understanding those processes in infants and children. The committee, however, remains concerned about the potential for long term harm from toxicity during development.

The third step - exposure characterization - explores who is exposed to the chemical, how often they are exposed and how much they receive. To accurately complete this step it is necessary to know what children are eating and the pesticide residues on those foods. While our knowledge about the diets of infants and children as well as the pesticide residues on those foods is limited, this is the area in which the committee found the greatest difference between infants, children and adults. The diets of infants and children are substantially and significantly different from those of adults. Infants and children frequently consume a smaller number of foods than adults. As a consequence of the consumption of a smaller number of foods plus the consumption of greater quantities of foods on a body weight basis - children frequently ingest single food items in amounts which are many times greater than adults. Indeed, the committee found differences in consumption of single food items to be the most significant difference - with respect to the potential for exposure to pesticides in foods - between infants, children and adults.

The fourth step - risk characterization - combines all of the information gathered in the three previous steps and calculates the risk across the population for adverse health effects from the chemical or chemicals of concern. In our evaluation of this step the committee examined the methodology used by regulatory agencies for quantitating risks to infants and children.

The committee observed that the methods used for characterization of risks were developed for use with adult animals, did not take into consideration the fact that infants and children are growing and developing and have different susceptibilities than adults, are exposed to multiple pesticides on a single food item or are exposed to the same pesticide or pesticides that act by the same mechanism on different foods and by different routes. To remedy this and improve the risk assessment methodology for infants and children the committee developed a risk assessment technique which combines:

1. data on the unique dietary patterns of infants and children,
2. data on pesticide residues in foods as eaten,
3. exposures in multiple different foods to the same pesticides,
4. exposures to different pesticides on the same or different foods that have the same mechanism of action.

Because toxicity testing in developing animals is inadequate, it was not possible to directly calculate risk to infants and children using this new methodology. However, we were able to use the method to calculate the exposures of infants and children to selected pesticides using this technique.

On the basis of the information I have summarized the committee concluded that: (i) the susceptibility of infants and children is indeed different from adults - in some cases greater, in other cases less, (ii) infants and children differ from adults in their potential for unique exposures - with differences in exposures being the most significant difference between children and adults, (iii) it is necessary to develop additional information on the toxicological characteristics of infants and children, (iv) the data on dietary exposures of infants and

children to pesticide residues in foods is inadequate and requires immediate changes in federal strategies for dietary surveys and analysis of those foods for pesticide residues.

The committee believes that the current regulatory framework allows an additional safety factor - which may be as large as 10-fold - for risks of developmental concern. The committee believes that the use of this safety factor, where appropriate, provides adequate protection for infants and children.

The goal of our report is to make the very good food supply of the United States even better. We have directed our report primarily to those who make decisions about pesticide use and those who regulate pesticides. We are not saying that parents should change their children's diets to avoid certain foods. We don't say that a particular food is dangerous for children and needs to be discarded. Parents should continue to emphasize a diverse selection of fruits and vegetables in their children's diets.

The committee does believe however that basic changes are needed in the current regulatory system to ensure that foods eaten by infants and children are safe. The major conclusion of this study is that the risk assessment process used by the federal government for pesticides does not pay sufficient attention to the protection of the health of infants and children. The government's current regulatory program does not recognize that children differ greatly from adults not only in size but also in metabolism and what they eat.

In summary, the committee believes that children deserve special consideration when it comes to pesticide regulation. By adopting the recommendations we have outlined in our report the federal government could go a long way toward ensuring that their health is not compromised by the food they eat.

Mr. Chairman, my colleague and I will be pleased to answer any questions.

**Testimony Before Committee on Agriculture Subcommittee
On Department Operations and Nutrition
United States House of Representatives
July 14, 1993**

**By: James N. Seiber
Sierra Pacific Professor of Environmental Sciences
and
Director, University Center for Environmental Sciences and Engineering
University of Nevada, Reno
Reno, Nevada 89557**

Good morning Mr. Chairman and members of the committee. My name is James N. Seiber. I am Director of the Center for Environmental Sciences and Engineering at the University of Nevada, Reno and, until 1992, Professor of Environmental Toxicology at the University of California, Davis. I served as a member of the Committee on Pesticides in the Diets of Infants and Children of the National Research Council released earlier in July, 1993. The Research Council is the operating arm of the National Academy of Sciences chartered by Congress in 1863 to advise the government on matters of science and technology.

There were fourteen members of the Committee with a variety of backgrounds. My input was largely in the areas of residue chemistry and exposure assessment. Dr. Mattison mentioned the primary conclusions and recommendations of the report:

- Despite an admirable safety record of our foods for all segments of the U.S. population, improvements in safety could accrue from exposure estimates which reflect the unique diets of infants and children and also non-dietary intake of pesticides.
- Health considerations should be given greater weight in decisions regarding tolerances, so that children (and their parents) could select diets which might contain inevitable residues without encroaching on safety margins.

- Better data on exposure should be combined with better data on harmful effects in order to improve the assessment of risks for infants and children from residues in their diets.

I wish to follow up Dr. Mattison's remarks focussing on the areas of residue data and exposure assessment. Clearly, for there to be a toxicological outcome there needs to be exposure to the toxicant, at levels which are above a 'no-effect' level. Unfortunately, we do not know with certainty what the precise exposure is, not for the average American and not for sub-populations of Americans such as infants and children. We also do not know precisely the 'no-effect' level for humans. These uncertainties have led to the use of safety factors in regulating residue intakes. But the margin of safety provided by these factors may vary for population subgroups, such as infants and children.

One of the more time-consuming chores the Committee undertook was to locate all the data bases of information relating to exposure, and then placing them on a common footing for interpretation. We found that there does not presently exist a comprehensive data source on pesticide levels in the major foods consumed by infants and children. A computerized and standardized data base for pesticide residue data is badly needed, so that we can determine the exposure of the 'average' American and also sub-populations such as children when issues of food safety arise.

Part of the problem is that analytical laboratories use differing procedures, catch differing numbers of the 600 or so registered pesticides and their breakdown products in their analyses, and vary in their way of reporting data. We felt that there should be more standardization in this system, for federal and state labs and for private labs. Labs which conduct multiresidue analysis of foods, for example, should use the same or similar multiresidue methods, or at least ones which include a broad cross section of chemical residues which may be present. Labs should also handle such issues as detection limits, non-detects, and data averaging in the same or similar ways, to ensure comparability of data.

Another problem is that much of the random surveys of residues are conducted on the raw agricultural commodity, rather than on food as consumed. Food processing and food preparation can dramatically alter (generally reduce) the residue on foods as consumed, but we found that data was not generally available on this point. An exception is infant formula, for which all surveys to date show no significant residues are present. We recommended that there should be a special market basket survey designed around the diets of kids, and that more research be done on the effects of washing, peeling, cooking, etc on residue levels.

Finally, many of the foods most consumed by infants and children are not sampled frequently enough by FDA and the states to get a comprehensive picture of what chemicals, and what levels of them, are in kids' diets. For example, the eighteen foods most frequently tested in FDA's Surveillance Program, include only four of the 18 major foods consumed by infants and children. There is also practically no data on residue intake from water used in preparing food items which could add to residue intake from the foods themselves.

The committee took the approach that improved methods of data analysis -- such as the use of distributions in calculating dietary exposure -- need to be incorporated in agency decisions. Because people vary greatly in their consumption patterns, and foods vary greatly in their residue contents, a convolution of distributions will provide information of greater specificity for population subgroups which may be at altered risk relative to the average.

We recommended further that the agencies focus more on combinations of chemicals rather than proceeding on a chemical-by-chemical basis in regulation. At least for some chemicals of a common mode of action, such as cholinesterase inhibition, the use of toxicity equivalents as a basis for assessing total exposure proved to be quite revealing. Exposures as high as 10 times the reference dose could be calculated for a small but significant number of people when all cholinesterase-inhibiting chemicals potentially present in foods were taken into account.

In conclusion, a safe American food supply can be made safer by changes in the way data are collected and analyzed. Our committee did not recommend changes in eating habits or food selection, nor did it recommend restriction of use of specific chemicals. Generally, we felt that a lowering of risk could be accomplished by the changes we recommend in data collection and regulatory procedures. Further improvements in assessing toxicity of chemicals toward the young, coupled with better data on exposure, could significantly lower risks of illness and disease for infants and children caused by pesticide residues in their diets.

TESTIMONY OF JOHN D. GRAHAM, Ph.D.

My name is John D. Graham. I am Professor of Policy and Decision Sciences at the Harvard School of Public Health and founding Director of the Harvard Center for Risk Analysis. I appreciate the opportunity to testify today on the crucial role of risk-benefit analysis in the regulation of pesticide products. Before beginning, please let me acknowledge my Center colleagues, Nancy Beaulieu, George Gray, Cynthia Lopez and March Sadowitz, for their help in preparing this testimony.

I would like to make two major points today.

First, the National Academy of Sciences has made several sound recommendations for improving the technical quality of pesticide risk assessments, particularly concerning the welfare of infants and children. These recommendations should be implemented by federal agencies as soon as possible.

Second, while recent public attention has focussed on the potential risks of pesticide residues on food, we should not ignore the benefits of pesticides. In fact, there is an urgent need for better scientific and public understanding of the potential benefits of using pesticides in various agricultural, commercial, and residential contexts.

Please allow me to elaborate briefly on each of these points.

First, the NAS report contains several constructive scientific recommendations. More and better quality exposure information are needed to clarify the potential risks of pesticide residues. Better understanding of the biological susceptibilities of children and young adults is also needed. As such information is obtained, it will become feasible for agencies such as the Environmental Protection Agency to introduce more rigorous methods of risk assessment into the regulatory process.

At the Harvard Center for Risk Analysis, we are enthusiastic about the promise of new distributional methods of risk assessment, such as those recommended in the NAS report. We believe they will provide regulators with more accurate and complete indications of the potential risks of human exposure to pesticides. We have already begun to demonstrate their feasibility through application to specific chemicals.

The NAS report emphasizes the need for analysis of variability in human exposures and biological susceptibilities to pesticides. We also believe that distributional methods should be used to express how confident scientists are in the reported estimates of risk from consuming pesticide residues. This kind of uncertainty analysis will help inform regulators and the public of the limitations of the available science and the most promising directions for future research.

My second and more important point is that, as a nation highly concerned with the safety of our food supply, we should not neglect the potential benefits of pesticide products. Some recent media stories have suggested, for example, that pesticides should be regulated only to protect the health of infants and children, without taking into account the benefits of pesticide use. This line of reasoning is not as protective of public health as it may seem to be.

If we were to ignore the benefits of pesticides and set tolerance levels to assure the maximum degree of protection for the public, we would be logically compelled to set zero tolerance levels in many cases. This would be necessary because there is no scientific test and no group of scientists, not even my former employer the National Academy of Sciences!, that can identify a nonzero level of chemical exposure that is completely safe. All exposures to chemicals, whether manmade or natural, carry some degree of risk, and we should not delude ourselves into thinking that our children can be made completely safe. Like all complex technologies in daily life, the responsible application of pesticides will inevitably present some risks that can only be justified by an informed, explicit, and accountable assessment of their benefits.

Were the benefits of pesticides to be ignored in the setting of tolerance levels, there is a real danger that the resulting legal conditions of pesticide use would be unduly stringent, such as would result from the more strict interpretations of the Delaney Clause. Although the benefits of pesticide use are not as well studied and understood as they should be, it is important to consider what might happen if the use of pesticides were terminated or phased out through stringent tolerance levels.

If farmers are suddenly unable to use pesticides, their crop yields (per acre) may decline due to insufficient pest control. Since the costs of producing the same level of output would then be higher, farmers would be forced to charge higher prices for the crops they produce. A recent study published in the journal *Science* indicated that the food price impacts of bans on pesticides could be quite substantial. I am submitting this study for the hearing record.

The benefits of lower food prices are not simply financial; they impact the health of parents and their children. For example, if higher prices for fruits and vegetables cause dietary habits to shift away from these foods, an increase in the risk of cancer, heart disease, and other diet-related diseases can be expected. This outcome is more likely among low-income populations, where price sensitivity is highest and knowledge of the health effects of poor nutrition may be lower.

In some situations, the loss of a pesticide may cause direct harm to public health as a result of consumer exposure to the fungi that thrive without the pesticide. For example, although many fungicides have been shown to cause cancer in animals at high doses, some of the toxins produced by fungi, such as aflatoxin, are also known to cause cancer. One of the benefits of pesticides is the human health protection resulting from destruction of fungi.

Even if farmers substitute new pesticide products for the products that are banned or restricted, the new products should be evaluated with care. Many new products are quite promising, but others are not as good as expected. For example, some replacement pesticide products have proven to be more acutely toxic to farmers and applicators, even though they do not leave significant residues on foods. The safety of farmers and farm workers needs to be carefully considered. Moreover, the next best alternative to using some carcinogenic pesticides is to use products that may not be carcinogenic but cause reproductive and neurobehavioral

effects in animals at high doses. Tolerances need to be set with the comparative risks of substitutes in mind. When considering tolerance levels for a new pesticide product, we should strive to minimize overall human and ecological risk per unit of crop production compared to the next best alternative product (even if the risks from the new product's food residues are relatively high!).

In the long run, it will be possible to reduce considerably the use of some traditional pesticides through alternative farming methods such as integrated pest management, use of biotechnology products, and organic farming. The promise of alternative agricultural methods deserve serious consideration, both in the marketplace and in public policy development. There is no question, however, that an abrupt termination of chemically-intensive agriculture could not be replaced by alternative methods without adverse price impacts and dislocations.

In the final analysis, our objectives in pesticide regulation are more complicated than simply setting tolerance levels to provide maximum protection to infants and children. We need to consider the impacts of tolerance levels on consumer health, food prices, farmer safety, and the welfare of low-income populations. A risk-benefit framework will show that some pesticides should have stricter tolerance levels or should be banned altogether. Others should be used more widely. The same kind of risk-benefit framework can also be used to inform appropriate transitions to alternative methods of agricultural production.

One can criticize the risk-benefit framework on the grounds that it asks regulators to make complex judgements based on a variety of considerations. That is certainly true. Despite its imperfections, a risk-benefit framework is the best tool we currently have to accomplish this challenging task of regulating pesticide use.

Thank you very much for the opportunity to testify and I would be happy to answer any questions that you might have.

(Attachment follows:)

Articles

The Economics of Pesticide Use and Regulation

DAVID ZILBERMAN, ANDREW SCHMITZ, GARY CASTERLINE,
ERIK LICHTENBERG, JEROME B. SIEBERT

Pesticides enhance agricultural productivity, but the environmental and health side effects of their use justify government regulation, a subject of continuing societal debate. Bans on pesticide use are the principal regulatory device used in the United States. The economic impacts of such bans depend on the availability of substitutes, supply and trade conditions, and research and development. Without substitutes, pesticide bans result in reduced production levels and higher prices, a substantial loss of discretionary income to consumers, and a redistribution of income among agricultural producers. Most food safety concerns can be addressed by establishing standards and markets for pesticide-differentiated products, but worker safety and clean water concerns will require direct controls. Pesticide-use fees are shown to be more efficient than outright pesticide bans as a mechanism to obtain environmental goals.

Pesticide use varies by crop, pest, and location. Estimated pesticide cost is approximately 3% of the gross farm value in California, or \$500 million. Cost revenue ratios vary from 1% (grapes and tomatoes) to 4% (oranges). Surveys suggest that California's agricultural pesticide-use levels for most crops are low relative to the rest of the United States and that California leads in the development and adoption of IPM.

Agricultural researchers have argued that pesticide-application strategies should take into account crop resistance and secondary pest problems. Economics would suggest the use of diversified pest management strategies such as monitoring pest populations, selective reliance on chemical pesticides, biological control, and cultural practices. Because of economic, health, and safety concerns, more than 50% of California farmers practice IPM in one form or another.

Productivity and Costs

Pesticide productivity has been estimated econometrically at different levels of aggregation (3). Although estimates vary widely, the incremental benefits of pesticide use far exceed the cost. A \$1 increase in aggregate pesticide expenditures has been estimated to raise gross agricultural output from \$3 to \$6.50. A number of omitted factors, such as application and monitoring, resistance, and health and safety costs, might explain this difference.

Econometric studies have provided estimates of the productivity of broad pesticide categories for various crops. Such estimates usually measure the impact of a proportional incremental change for all pesticides within a category, whereas most policy analyses require impact estimates of specific chemical bans. Impact assessment should incorporate productivity estimates into market interaction models to show the effects of regulations on prices, land use, production, trade patterns, and the costs to society.

The partial budgeting approach is often used by government agencies to assess the impacts of banning pesticides. It relies on results of experimental studies to estimate cost and yield effects per unit of land. These effects are then summed across crops and regions to provide aggregate cost estimates. This approach tends to ignore possible price and land-use changes; it also tends to overestimate effects on growers, while underestimating consumer effects. An alternative approach obtains and aggregates the yield and cost effects of the regulations to estimate the effect on producer supply. These results are then incorporated into a system of supply and demand equations representing the forces that shape market outcomes. Solution of these equations approximates the impact of pesticide regulations.

Lichtenberg, Parker, and Zilberman (4) used this approach to

THE USE OF SYNTHETIC ORGANIC PESTICIDES IN AGRICULTURE has expanded production possibilities and benefited farmers, processors, and consumers (1). Increasing concerns for environmental degradation, worker safety, and public health have spawned intense political debate over pesticide use. To examine this issue, we assess productivity and costs, trade-offs, and policy alternatives for U.S. agriculture, focusing primarily on California, the largest and most diverse agricultural state.

There has been explosive growth in pesticide use in the post-World War II period. The use of herbicides, insecticides, and fungicides in the United States during the last 25 years is charted in Fig. 1. Nearly 75% of herbicides are used on corn, soybeans, and cotton, sometimes as part of a low-tillage strategy. The recent decline in herbicide use is partly due to a reduction in farmed land and to an increase in herbicide cost. The decline in insecticide use during the 1980s is explained by the introduction of more potent materials (synthetic pyrethroids) and the adoption of integrated pest management (IPM) practices that use insecticides more selectively (2). Fungicide use has remained relatively stable during the 1970s and 1980s. Most fungicides, which affect quality, storability, and yield, are used on fruits and vegetables.

D. Zilberman, A. Schmitz, G. Casterline, and J. B. Siebert are in the Department of Agricultural and Resource Economics, University of California, Berkeley, CA 94720. E. Lichtenberg is in the Department of Agricultural and Resource Economics, University of Maryland, College Park, MD 20742.

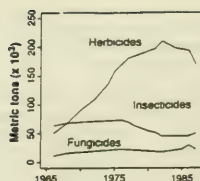


Fig. 1. Pesticide use in the United States (18).

study the impact of canceling ethyl parathion, one of the many pesticides used in California lettuce production. To account for seasonality, markets for lettuce in winter, spring, summer, and fall were modeled separately. Producer groups were categorized according to region, type of pest problem, and whether or not they used parathion. Areas treated with parathion and its substitutes were estimated from reported usage data. Estimates of the effect of canceling parathion at the field level were obtained from a study in California (5). Prices and consumption levels were taken from government statistics; supply and demand parameters were obtained from various available sources.

The anticipated effects of canceling parathion are shown in Table 1. Consumer and producer surpluses are used to calculate the consumer and producer effects. The consumer surplus approximates, in monetary terms, the difference between the benefits derived from a certain consumption level and the cost at the market. The producer surplus is a measure of profits (6). Parathion bans will result in higher prices and lower output, making consumers worse off. Because of higher prices, users of parathion (35% of farmers) suffer significant losses, whereas nonusers gain. Overall, lettuce producers lose.

Extrapolating from Table 1, the annual loss to consumers is about 3.8% of current spending on lettuce. The loss to producers is about 2.9% of their annual revenues. The per capita impact on each consumer is small (lettuce takes a minor share of their spending), whereas impacts on some producers may be significant because net income often does not exceed 10% of producers' revenues.

On the basis of this California study, we can suggest the following generalizations about factors affecting the impact of pesticide bans.

1) *Availability of substitutes.* The immediate effect of canceling a pesticide is a shift to chemicals that are usually more expensive or less effective, or both. When differences in cost and efficacy are small, the economic impacts are small. However, when effective substitutes are not available, the impacts may be large. Although more costly, substitutes were available for all parathion uses in lettuce except one—the control of lettuce root aphids in California's central coast, a major lettuce-producing region in summer and spring. Without parathion, yields in this region were estimated to drop by 25%.

Were a substitute available, the impact of canceling parathion on output would be negligible and the annual average lettuce price would increase by only 0.10% as compared to a 3% increase without a substitute.

2) *Capacity for additional supply.* One major effect of banning a pesticide is to shift production to different regions in response to increased product prices. In spite of the 25% yield reduction in a major region, the aggregate impact on lettuce output is only 0.50%. Because of increased prices, nonusers increase lettuce production, almost compensating for lost output. The ban also redistributes income among producers—for each dollar users lose, nonusers gain 40 cents.

3) *Responsiveness of demand to prices.* As demand becomes inelastic, pesticide-use bans are likely to have a greater price effect. A ban on parathion is estimated to reduce annual lettuce production by 0.50%, but the estimated price effects are substantial. The average price of lettuce is estimated to rise by 3%, while the summer price increases 9%.

4) *Trade.* If exports account for a large share of demand, foreign consumers will bear a large share of the cost. International trade considerations play a minor role in the lettuce case because only 5% of production is exported. In a companion study (4) of the impacts of canceling parathion on almonds (55% of which are exported), the loss to foreign consumers was estimated to be substantially higher than that to domestic consumers.

In the long run, the increased cost of U.S. products may spur entry by foreign producers and erode the ability of the United States to shift the cost of environmental regulation abroad. Moreover, reduced exports would exacerbate the balance-of-trade problem.

5) *Research and development (R&D).* When pesticide bans are accompanied by extensive R&D efforts, substitute pest treatments may be developed to mitigate the initial effects of the ban. If a substitute is found for parathion in the treatment of the lettuce root aphid problem, the reduction in summer and spring outputs will become less than 45,000 metric tons for each season, and the overall cost of canceling parathion would be 10% of the current estimates (Table 1).

Impacts of Wholesale Pesticide Bans

There have been recent proposals to ban pesticide use in agricultural systems; Proposition 128 (popularly known as "Big Green"), a bond and initiative statute defeated on the California ballot in November 1990, was one such proposal. Proposition 128 would have phased out food-use pesticides known to cause cancer or reproductive damage. When a group of chemicals is banned, pesticide substitution possibilities and yields are reduced more than when just a single chemical is banned. A recent study (7) found that there were no substitutes for 30% of the pesticides that would have been

Table 1. Seasonal effects of banning parathion for lettuce. Costs are measured by the change in producer revenue for parathion users and nonusers in consumer expenditures on lettuce (3).

Season	Output (metric tons $\times 10^3$)		Price (dollars/metric ton)		Cost (dollars $\times 10^6$)			
	Pre-ban	Change	Pre-ban	Change	Users	Nonusers	Consumers	U.S. total
Winter	704	-0.1	244	0.2	-0.2	0.1	-0.2	-0.3
Spring	783	-5.4	248	13.0	-14.2	6.6	-9.7	-17.3
Summer	684	-7.1	252	22.0	-16.7	7.7	-14.3	-23.3
Fall	650	-1.3	299	5.1	-6.0	1.7	-3.2	-7.5
Year	2821	-13.9	256*	10.8*	-37.1	16.1	-27.4	-48.4

* Figures represent annual averages.

banned if Proposition 128 had passed.

Pesticide bans in fruits and vegetables. California is a major producer of fruits and vegetables that would be affected by Proposition 128. The five crops shown in Table 2 generate 46% of California fruit and vegetable revenue. We estimated the proposition's economic effect for these five crops, taking into account the uncertainty regarding key parameters. For each crop, there were five alternative estimates of the proposition's yield effects. These estimates were based on alternative interpretations of the law itself and on assumptions regarding California agriculture (8). Five demand and three supply price elasticities were used for each crop. The impact of the proposition on each crop's price, output, producer revenue, and consumer spending was computed under each possible scenario. We generated estimated distributions of the various outcomes. The means and high values of these distributions are presented in Table 2 (9).

Consumers bear most of the cost of the proposition. The expected value of consumer loss is about 25% of current expenditure on the five crops, and there is a 5% probability that this ratio will be above 52%. Estimated average impacts on producers vary among crops, but the aggregate expected loss is only 0.6% of crop revenue. However, there is a 5% probability that producer loss will be 12% of revenue; this may exceed net income. In spite of the modest impact of Proposition 128 on expected profits, the desire to avoid risking large losses may explain why many farm groups objected to it.

The large price effect for lettuce may be explained by its highly inelastic demand. The expected income of lettuce growers actually increases because the higher price more than compensates for the reduction in output. Tables 1 and 2 show that the consumer cost effect of a wholesale pesticide ban, relative to a selective ban, is of a much larger order of magnitude.

Pesticide bans in field crops. It is interesting to compare the estimated impacts of the California fruit and vegetable pesticide bans to those of large-scale pesticide bans for other crops. Assuming the prevailing economic and policy conditions, Knutson, Taylor, Pen-son, and Smith (10) estimated the economic impacts of complete pesticide bans on eight major U.S.-produced commodities. The estimated cost increases and yield decreases were substantial but, because of increased planting and land-use pattern shifts, the output reductions were smaller (Table 3). The aggregate net income of the agricultural sector is predicted to increase slightly; income distribution, however, is predicted to change drastically. Because of price effects, the income of the crop sector is predicted to increase by 18% but, due to higher feed costs, the income from the livestock and poultry-producing sectors will decline by 27%. Because of the ban,

consumers are estimated to have an \$18-billion annual loss; however, this translates to less than a \$90 annual increase in food costs per consumer. This is a 6.5% increase in the food expenditures of the average consumer, but the relative impact on those with lower incomes will be much higher.

The estimates obtained in this study (10) were probably high. Inflated cost and yield impact estimates were used and extensive restrictions on imports were assumed (11). Another economic gain that must be considered is the reduction in government price-support expenditures due to price increases associated with the pesticide ban. Adjusting for this effect could reduce the cost of pesticide regulations by up to 30% (12). Also, for commodities such as rice and barley, where the United States is not an internationally dominant producer, price effects may have been overstated. In spite of these limitations, the study (10) demonstrates the importance and magnitude of structural and distributional changes resulting from pesticide bans. It provides a quantitative perspective on the value and role of pesticides used on major agricultural commodities grown in the United States.

The studies described above have generally reached similar conclusions regarding the short-run impacts of a hypothetical large-scale ban of pesticide use in the United States. The price of most commodities is expected to rise sharply, while consumers would have the largest total loss. However, the annual cost of pesticide bans on field crops, fruits, and vegetables to the average consumer would be above \$100, but less than 10% of the total food expenditure. The aggregate effect on producers is not expected to be large, but the ban may lead to a substantial redistribution of income among producer groups; some groups may gain significantly but other groups could experience devastating losses.

The redistribution of income among producers partly reflects the reallocation of production capacities. Expansion and adjustment in land and other input uses cause the impact of bans on output to be smaller than the predicted yield effects. Redistribution of production by location is especially important for major agricultural commodities. For example, regulation of pesticide use in California cotton may lead to increased production in the southeastern United States; this would serve to moderate output and price effects. Similarly, short-run increases in fruit and vegetable prices would likely lead to increased production in Arizona, Texas, Florida, Mexico, and other regions—eventually causing prices to fall. In particular, lettuce production would tend to shift to other regions, causing California growers to lose. Thus, in the long run, consumer loss would be reduced, producer income outside California would rise, but Cali-

Table 2. Simulated impacts of a pesticide ban on five crops in California.

Crop	Impact	Output change (%)	Price change (%)	Producer revenue (dollars $\times 10^6$)	Consumer spending (dollars $\times 10^6$)	Total effect* (dollars $\times 10^6$)	Initial revenue (dollars $\times 10^6$)
Almonds	Mean	-15	21	-1	-94	-95	490
	High†	-34	59	-100	-256	-221	
Grapes	Mean	-19	29	-52	-358	-410	1508
	High†	-52	87	-365	-1031	-1123	
Lettuce	Mean	-9	57	130	-321	-191	832
	High†	-28	175	-81	-931	-607	
Oranges	Mean	-21	13	-52	-53	-105	458
	High†	-41	29	-115	-114	-204	
Strawberries	Mean	-25	18	-47	-57	-104	392
	High†	-53	37	-107	-114	-220	
Five crops	Mean			-22	-883	-905	3480
	High†			-422	-1809	-1753	

*The total effect is the sum of the change in producer revenue and consumer spending. This holds exactly in the mean but, because the high estimates for consumers and

producers correspond to different situations, the sum is not exact for the high effect. †The high estimate is that value which may be exceeded with a 5% probability.

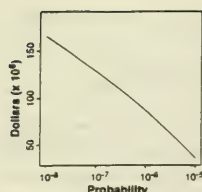


Fig. 2. The curve represents the estimated trade-off between the cost of producing pure water and incremental cancer risk for DBCP in well water, Fresno County, California. Risk is measured by the annual increase in the probability of a Fresno County resident contracting cancer. The curve depicts the lowest cost necessary to provide water at the given risk level (1).

fornia agriculture would be the main loser.

Some of the negative impacts of the pesticide ban may be mitigated by new technologies. Increased commodity prices are likely to spur private R&D efforts and accelerate their adoption. Nevertheless, the capacity to develop such alternatives should not be overestimated (13); private R&D efforts are likely to be insufficient, especially for specialty crops that generate small volumes of pesticide sales. Massive publicly financed research would likely be necessary, and new discoveries could be long in coming. Wholesale restrictions, such as Proposition 128, would generate a need for new classes of pest control chemicals. Hence, the broader the imposed restrictions, the lengthier and more arduous the process of adjustment.

Trade-Offs

A full assessment of the economic impact of pesticide bans must consider indirect effects, such as problems of food safety, worker safety, and environmental quality.

Food safety. Recent reports by the Environmental Protection Agency (EPA) Science Advisory Board state that human health risks from pesticide exposure in food residues are relatively low. These reports suggest that food safety concerns are primarily problems of perception and preference. In addition, while consumers may be concerned about eating fresh produce sprayed with pesticides, their willingness to pay for such produce varies. In his survey of Atlanta shoppers, Ott (14) found 61.5% of consumers were ready to accept more cosmetic defects to ensure pesticide-free produce. Furthermore, only 10% of consumers were willing to pay more than 10% extra for pesticide-free produce. This can be contrasted to the 1990 weekly average price premium of 100% commanded by organic (chemical-free) romaine lettuce in Los Angeles (15).

In light of these findings, the government plays a valuable role in testing, assessing, and providing information regarding the health effects of consuming pesticide-treated foods. In most cases, the food safety problem can be best addressed by the marketplace, with the establishment of differentiated markets for organic or pesticide-free products. Government regulations may be used to monitor and establish standards for such products.

Pollutants and worker safety. The EPA Science Advisory Board found that worker occupational hazards and pollutants in drinking water were among the major risks to human health in the United States and that reduction of these risks justifies government policies that affect pesticide use and related activities. Such policies include bans on chemicals, use restrictions, pesticide fees, subsidies for nonchemical pest management practices, protective clothing, and application standards.

Lichtenberg and Zilberman (16) introduced and applied a framework constructing the trade-offs between costs and risks associated with pesticide-related policies. The estimated trade-off between the costs and risks resulting from alternative regulations to control

Table 3. Percent change in performance measures due to pesticide bans on major commodities (10).

Measure	Wheat	Barley	Rice	Corn	Cotton	Soybean	Sorghum	Peanut
Yield	-25	-29	-57	-32	-39	-37	-20	-70
Production	-9	-12	-39	-18	-30	-26	4	-17
Price	6	23	83	38	34	100	13	146
Export	-15	-22	-64	-26	-46	-50	-35	-8

1,2-dibromo-3-chloropropane (DBCP) residue in drinking water in Fresno County, California, is shown by the curve in Fig. 2. Risk was assessed by measuring the average increase of a Fresno County resident's annual probability of contracting cancer. The negative slope of the curve indicates that reducing risk is more costly. The curve represents policies that attain certain risk levels at minimum cost or result in the lowest risk level for a given expenditure. The area above the trade-off curve represents inefficient policies, because other policies can attain the same risk level with lower costs, or can cost the same but result in lower risks.

Uniform regulations, imposing the same standard of performance at all locations, tend to be inefficient. In the case of the Fresno DBCP study, efficient policies varied the requirements for water providers according to their per capita costs of filtering or replacing existing water sources.

Lichtenberg, Spear, and Zilberman (17) analyzed the impacts of worker safety regulations that restricted reentry into apple orchards after treatment with organophosphate insecticides. Such treatment serves to protect apples from codling moth larvae infestations before harvest. Exposure to the insecticide residue may cause poisoning. Longer reentry restriction periods increase degradation of the residue to nontoxic by-products, but also reduce profits. Efficient reentry restriction schemes were found to be highly nonuniform. They required longer restricted reentry periods in California, which has drier summers, than in Washington and Michigan.

Policy Alternatives

A complete ban of a chemical (or group of chemicals) is a uniform policy. Such a ban does not discriminate between situations where the elimination of a chemical would result in major or minor cost increases. In many cases, a substantial share of the environmental and health benefits associated with a complete ban can be preserved by introducing a partial ban or a restrictive-use policy. In such cases, pesticide use is allowed only in situations where substitutes are poor or nonexistent. For example, when parathion use in lettuce is permitted only for growers in California's central coast region, parathion use in the United States is reduced annually by more than 80%. The total economic cost of a partial ban drops below \$0.5 million for the spring, summer, and fall seasons, compared to \$17, \$23, and \$7 million (Table 1) for each of these seasons under complete bans. The price effect of this partial parathion ban is insignificant for all seasons, unlike a complete ban which leads to 5% and 9% price increases in the spring and summer.

Pesticide fees or taxes can have effects similar to those of partial-ban, limited-use policies. Fees increase pesticide prices, encouraging farmers to become more selective in their chemical choices and to switch to other options as they become relatively more cost-effective. For lettuce, fees that raise the cost of parathion use by \$30 per hectare are likely to have the same effect on the profit-conscious grower as the partial ban policy suggested earlier.

Fees can restrict environmental and health risks below target levels

at the least cost. Uniform pesticide regulation may be much more costly than fees in attaining policy targets. Furthermore, when the health costs of risk can be enumerated, the most efficient fee or tax policies are those that equate the incremental benefits of risk reduction to the incremental costs of reduced economic activities. It is advisable to use the proceeds of pesticide-use fees or taxes to finance R&D efforts when developing alternative pest-management practices, subsidizing their adoption, and addressing negative side effects from pesticide use.

Establishing mechanisms for monitoring and enforcing environmental regulations has always been an administrative challenge. The organizations established to implement pesticide registration requirements in some states (most notably, California) provide the base to administer pesticide taxation policies. The derivation and assessment of policy parameters will require much more "policy-relevant" research and more interdisciplinary cooperation among managerial, agricultural, and environmental health scientists.

REFERENCES AND NOTES

1. D. Zilberman and J. B. Siebert, Eds., *Economic Perspectives on Pesticide Use in California* (Working Paper 564, Department of Agricultural and Resource Economics, University of California, Berkeley, 1990).
2. G. A. Carlson in (1), chap. 3.
3. C. Carrasco-Tauber in (1), chap. 6.
4. E. Lichtenberg, D. D. Parker, D. Zilberman in (1), chap. 7.
5. N. C. Toscano, K. Kido, C. Giorgio, unpublished paper.
6. R. E. Just, D. L. Hueth, A. Schmitz, *Applied Welfare Economics and Public Policy* (Prentice-Hall, Englewood Cliffs, NJ, 1982).
7. F. G. Zaloni and J. F. Strand, *Calif. Agric.* 44, 16 (1990).
8. J. A. Hewitt, S. O. Archibald, S. J. Moos, "A short-run welfare analysis of pesticide bans in California agriculture" (Food Research Institute Working Paper, Stanford University, 1991); D. Pimentel, unpublished paper; GRC Economics, unpublished paper.
9. For this high value, it is assumed that the impact is distributed normally and is the 95th percentile of the outcome distribution.
10. R. D. Knutson, C. R. Taylor, J. B. Peterson, Jr., E. G. Smith, *Economic Impacts of Reduced Chemical Use* (Knutson & Associates, College Station, TX, 1990).
11. H. Aver and N. Conklin, *Choices* 4, 24 (1990).
12. E. Lichtenberg and D. Zilberman, *Am. Econ. Rev.* 76, 1135 (1986).
13. L. Richardson, *Calif. Farmer* 273, 2 (1990).
14. S. L. Orr, *Agriculture* 6, 593 (1990).
15. U.S. Department of Agriculture, ERS, *Food Rev.* 14, 1 (1991), p. 43.
16. E. Lichtenberg and D. Zilberman, in (1), chap. 12.
17. E. Lichtenberg, R. C. Spear, D. Zilberman, in (1), chap. 11.
18. U.S. Department of Agriculture, 1990 Chartbook, *Agriculture Handbook No. 689* (Washington, DC, 1990).
19. This study was supported in part by the Environmental Protection Agency. We gratefully acknowledge editorial assistance from A. Nolan, M. R. Graham, and H. C. Schmitz. Giannini Foundation Paper no. 989.

**TESTIMONY OF DR. CARL K. WINTER,
EXTENSION FOOD TOXICOLOGIST,
UNIVERSITY OF CALIFORNIA-DAVIS**

**U.S. House of Representatives
Committee on Agriculture
Subcommittee on Department Operations and Nutrition**

July 14, 1993

I am Dr. Carl Winter and I am a food toxicologist on the faculty of the Department of Food Science and Technology at the University of California at Davis. I am also the Director of the University's FoodSafe Program, which was established in 1992 to facilitate the development and sharing of research-based food safety information. The program receives no funding from the agricultural, chemical, and food industries or from government agencies. The views expressed today are my own and do not represent an official position of the University of California.

I wish to focus my comments on the recent National Research Council report on "Pesticides in the Diets of Infants and Children." In general, I was quite pleased with the report. There is no doubt that the scientific basis for the assessment of dietary risks from pesticides, particularly with respect to infants and children, can be significantly improved. The recommendations in the report provide a blueprint from which improvements may be incorporated into the risk assessment and regulatory processes.

I do take issue, however, with the recommendation in the report that the EPA modify its decision-making process for setting tolerances so that the tolerances are based more on health considerations than on agricultural practices. While this recommendation may seem quite reasonable, closer examination leads me to conclude that this recommendation is inappropriate.

The process of establishing pesticide tolerances is enormously complex and is

the subject of a paper I published in *Regulatory Toxicology and Pharmacology* in 1992 examining the relevance of tolerances as safety standards. A copy of the paper has been submitted for the record. A major conclusion of the paper was that food safety proposals aiming to reduce tolerances on the basis of health could result in little benefit to public health but may lead to unwarranted restrictions on domestic and international agricultural practices. This conclusion results from the fact that pesticide tolerances serve important roles as enforcement tools to determine if pesticide applications have been made in compliance with regulations and should not be confused as indicators of potential health effects. Asking pesticide tolerances to serve roles as health standards would eliminate their effectiveness as enforcement tools and regulators of international trade.

If tolerances are to be set as safety standards, it is likely that the vast majority of tolerance levels would **Increase**, often significantly, rendering the tolerances ineffective as enforcement tools. This is based upon the findings, as are documented in the aforementioned article, that theoretical lifetime exposure to residues of most pesticides at the tolerance levels is well below established health criteria. In addition, in cases where tolerances were reduced, growers using pesticides properly could not be assured that residue levels would fall below the new tolerances; such instances could have significant legal repercussions. Finally, the reduction of specific pesticide tolerances could have dramatic effects upon international trade since food producers importing into the United States are subject to the same tolerances as those producing domestically. Reciprocal reductions in tolerances in the international community could result, leading to non-tariff trade barriers for United States food exporters.

Effective and efficient pesticide regulatory programs must be based upon sound scientific principles if unacceptable risks are to be controlled while benefits from pesticide use are maintained. Consistent with this goal, I offer the following four suggestions:

- 1) Pesticide tolerances should remain in effect as enforcement tools and

should not serve a dual role as safety standards. If a solid scientific case can be made indicating that the specific uses of a pesticide may pose unacceptable dietary risks, the tolerances for those uses should be denied rather than reduced to health-based levels. In the course of determination of the acceptability of the risks, risk assessors must be allowed the flexibility to use realistic rather than theoretical data when it is available.

2) Health-based standards, which I will call "action levels," should be established as companions to the tolerances and should represent pesticide- and commodity-specific residue levels of toxicological concern. Determination of appropriate action levels is a complicated process. Factors to consider include the likely contribution of residues of a specific pesticide from other commodities and contributions of other pesticides that produce similar toxicological effects. The differentiation of short-term and long-term risks and of cancerous and non-cancerous effects should be considered as well.

3) Once action levels have been established, they can be used to help prioritize pesticide and commodity combinations of greatest health concern. This, in turn, could guide regulatory monitoring programs to make such programs more relevant to health. Currently, monitoring programs are designed primarily to enforce tolerances. Since tolerances are not health-based and since illegal residues rarely constitute unsafe residues, existing monitoring programs are of little value in consumer protection.

4) As a scientist, I am favorably impressed with the recent NRC report and commend the NRC committee for fairly and responsibly identifying weaknesses in our present system of risk assessment and pesticide residue regulation. The recommendations made in the report to improve risk assessment methods are innovative and based on solid science. It should be pointed out, however, that implementation of the committee's recommendations will require significant expense, since the committee recommends major changes in the procedures from which food

consumption and pesticide residue data are obtained, toxicological studies are performed, and risks are estimated. Just as it is critical that the benefits from pesticide use be weighed against their risks, we must also consider whether adoption of the NRC committee's recommendations will provide an appropriate increase in consumer protection. Considerable scientific debate exists as to the actual health risks from pesticides since risk assessment is such an imprecise science and since appropriate data for use in risk assessment are often not available. From an overall perspective, however, few would argue that the risks from pesticides in the diet are of significant concern when compared with the risks of microbiological food contamination, malnutrition, and even naturally-occurring food toxins. With respect to pesticide issues, most agree that worker risks and environmental effects are of much greater concern than food residues. While improvements in dietary pesticide risk assessment and regulatory practices are welcomed by the scientific community, I believe that society would be better served if resources were directed towards programs investigating ways to reduce the use of agricultural pesticides rather than towards ambitious dietary pesticide risk assessment and regulatory programs.

Thank you for providing me the opportunity to share these views.

(Attachment follows:)

Pesticide Tolerances and Their Relevance as Safety Standards

CARL K. WINTER

*Department of Food Science and Technology, University of California, Davis, California 95616**Received November 12, 1991*

Following an investigation of the relationship between pesticide tolerances and safety, it is concluded that pesticide tolerances are not relevant as safety standards. This conclusion is based upon the findings that theoretical exposures to legal levels of pesticides in the diet may pose greater than negligible risks, while exposures to most illegal residues are of no apparent toxicological significance. Thus, the common and logical views that "legal" residues are "safe" while "illegal" residues are "unsafe" are not supported by scientific evidence. Pesticide tolerances do serve important roles as enforcement tools, and tolerance enforcement programs are useful in the regulation of international trade and provide economic disincentives that may discourage pesticide misuse and emphasize compliance with regulations. Since tolerances are not appropriate as safety standards, however, legislative food safety proposals focusing upon revocation or reduction of tolerances and upon increasing enforcement capabilities may result in little benefit to public health. © 1992 Academic Press, Inc.

INTRODUCTION

There is much current public and legislative concern regarding the presence of pesticide residues in food. A recent consumer attitude survey indicated that 80% of American shoppers consider pesticide residues to be a major concern (Opinion Research Corporation, 1990). The current level of public concern may be traced, at least to some extent, to several incidents and reports that have emerged in the past few years. These include the California aldicarb poisoning incident of 1985, in which illegal applications of the insecticide aldicarb were made to watermelons and resulted in over 1000 human cases of probable or possible pesticide poisoning (Centers for Disease Control, 1986). Notable reports include the 1987 study of the National Research Council (NRC) that presented cancer risk estimates from pesticides in foods using worst-case assumptions in an effort to examine the existing statutory basis for establishing legal levels for pesticide residues (NRC, 1987) and the widely publicized report of the Natural Resources Defense Council (NRDC) in 1989 alleging "intolerable" risks to children due to exposure to residues of cancer-causing (i.e., Alar) and neurotoxic pesticides in food (NRDC, 1989). In addition, reports from federal and state legislative bodies have soundly criticized regulatory programs for being unable to provide adequate

protection of consumers from pesticide residues (United States General Accounting Office, 1986a, 1986b; California Assembly Office of Research, 1988).

Numerous concerns have been raised as interest in pesticide food safety issues has increased. These include an awareness of the existence of toxicology data gaps for a large number of pesticides, the potential for "inert" ingredients of potential toxicological significance to leave residues on foods, the questionable reliability of food consumption estimates used in dietary pesticide risk assessments, and health concerns for infants and children as particularly sensitive population subgroups. In more general terms, however, the issues boil down to two major questions: (a) do pesticide tolerances provide adequate protection of the population? and (b) are enforcement programs adequate to ensure public protection? This is evident in recent legislative activity, where proposed legislation has primarily focused upon modification and/or revocation of existing tolerances and upon increasing enforcement capabilities as a means of increasing the safety of the food supply.

These questions imply, as common sense would dictate, that pesticide tolerances serve a function as food safety standards. In actuality, however, the processes by which pesticide tolerances are established are complicated ones, and the health significance of tolerances appears to be poorly understood. This paper examines the relevance of pesticide tolerances as "safety standards," discusses the implications of continued reliance on tolerances as indicators of food safety, and offers suggestions as to the proper interpretation of pesticide residue data in relation to tolerances.

ESTABLISHING PESTICIDE TOLERANCES

The United States Environmental Protection Agency (EPA), under the provisions of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), is authorized to grant pesticide registrations and to regulate pesticide uses and residues in food and in feed. The EPA will grant a pesticide registration following an assessment of the health, economic, social, and environmental costs and benefits associated with the use of the pesticide if the agency determines that the benefits will outweigh the risks.

To register a pesticide for use on a food crop, the manufacturer of the pesticide must provide the EPA with results from a comprehensive series of studies of acute and chronic toxicity, carcinogenicity, teratogenicity, mutagenicity, metabolic fate, and effects on nontarget organisms. In addition, studies of the environmental fate of the pesticide, including residue studies, are required. Results from these latter studies allow the EPA to make preliminary assessments of the level of human and environmental risk associated with the use of the pesticide to aid in the EPA's determination of the relationship between pesticide risk and pesticide benefit.

If the use of a pesticide is considered to have the potential to leave a residue on food or feed items, the EPA, under the provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA), is required to establish a "tolerance" representing the maximum legal residue for the pesticide on specific items. If residues are detected that exceed the established tolerances, or if residues of pesticides are encountered on items for which no tolerances exist for the pesticides, such residues are considered to be illegal and items containing the illegal residues are subject to seizure.

Studies to Support Tolerance Petitions

The procedures used to determine the actual tolerance levels are confusing and are often misunderstood; thorough knowledge of such procedures is critical for an un-

derstanding of the relevance of tolerances as safety standards. Generally speaking, a pesticide tolerance is set to accommodate the maximum residue expected from the legal use of the pesticide under conditions of maximum application rate, maximum number of applications, and minimum preharvest intervals. As such, pesticide tolerances serve as enforcement tools, and illegal residues serve to indicate pesticide misuse and/or inadvertent contamination of food or feed items due to drift, plant uptake from soil, or other environmental factors.

Comprehensive descriptions of the procedures used to establish pesticide tolerances and actual examples of the procedures are provided by Chaisson *et al.* (1987) and by Moore (1987). For pesticides leaving residues on raw agricultural commodities, several field studies in different geographical areas are performed under the most severe legal conditions of application in an effort to determine the maximum residue expected; the manufacturer of the pesticide will then petition the EPA to establish a tolerance in excess of the maximum residue found.

An analysis of field data submitted for establishment of tolerances for the fungicide captan on a variety of commodities and comparisons with actual regulatory monitoring data has been performed by Chaisson *et al.* (1987) and is summarized in Table 1. The data clearly demonstrate that tolerance levels are poor indicators of the actual amount of residue present following pesticide application and suggest that substantial misapplication of pesticides is typically required for residue levels to exceed tolerances. Similar findings relating the average residues found in controlled field studies to tolerances have been reported by McCarthy (1991).

Additional studies are required by pesticide manufacturers if the raw agricultural commodities to which the pesticides are applied may also exist in a processed form. Tomatoes, for example, may exist in a variety of processed forms such as tomato sauce, tomato paste, spaghetti sauce, pizza sauce, and vegetable juice as well as in their raw form. Processing studies are performed to determine whether residues may concentrate during processing. If residues do not concentrate, the tolerance will be established at the level established for the raw agricultural commodities. If, on the other hand, residues are shown to concentrate, the manufacturer will petition the EPA to grant a separate food or feed additive tolerance set in excess of the maximum

TABLE I
SUMMARY OF CAPTAN RESIDUE DATA FROM CONTROLLED FIELD STUDIES
AND FROM CALIFORNIA MONITORING PROGRAMS^a

Commodity	Tolerance (ppm)	Anticipated residue (ppm) ^b	Maximum observed level (ppm) ^c
Almonds	2	0.14	<0.01
Apricots	50	4.98	5.0
Cherries	100	18.59	20.0
Nectarines	50	2.17	<0.01
Peaches	50	6.59	10.0

^a Source: Chaisson *et al.*, 1987.

^b Average residue from controlled field studies using most severe legal application conditions.

^c Maximum residue detected from California Department of Food and Agriculture monitoring programs, 1981-1984.

residues expected (Trichilo and Schmitt, 1989). In general, the EPA requires a food or feed additive tolerance if the pesticide residues concentrate by 10% (1.1X) or more during processing (Moore, 1987).

Animal feeding studies will also be required if the pesticide is used on feed items or is applied directly to livestock. These studies are designed to develop data on the transfer of residues to products such as meat, milk, poultry, and eggs. Doses used in the feeding studies are typically set at the feed tolerance level, and at 3 and 10 times the feed tolerance level (Moore, 1987). Animals are dosed for 30 days, or until residues plateau in milk and eggs, and are sacrificed soon after the final dosage. The tissues that may be consumed as food are analyzed for the pesticide and significant metabolites, and the manufacturer will petition to establish a tolerance based upon the feeding study results.

Relating Tolerances to Toxicology Data

Perhaps the most confusing aspect of the tolerance establishment process is the EPA's practice of relating pesticide tolerances to toxicology data. Before approving a tolerance petition, the EPA estimates potential human dietary exposure to the pesticide and compares this estimate with established health criteria.

For nononcogenic effects, the health criterion considered is the acceptable daily intake (ADI) or, more recently, the analogous reference dose (RfD). The calculation of ADIs and RfDs is based upon identification of the no observable effect level (NOEL) from animal toxicology studies, which represents the highest dose *not* shown to have any effect in the most *sensitive* animal species tested. Not all measured effects are necessarily adverse health effects, however, and a no observable adverse effect level (NOAEL) may also be determined. The NOEL and NOAEL values are generally established from chronic (long-term) feeding studies. Due to difficulties in inter- and intraspecies extrapolation, the NOEL or NOAEL is divided by a safety factor (range, 10–10,000, most commonly 100) to yield the ADI or RfD, which represents the maximum daily exposure (usually over a 70-year lifetime) to a pesticide that would pose no apparent risk. Lists of pesticide ADIs and RfDs are compiled by the World Health Organization/United Nations Food and Agriculture Organization and the EPA.

For oncogenic pesticides, since current regulatory theory holds that oncogenic effects do not have NOELs and therefore cannot be related to ADIs or RfDs, cancer potency factors, known as Q^* s, are derived. The Q^* represents the slope of the dose-response curve from animal studies yielding a positive oncogenic response. The values for Q^* s are considered to be highly conservative (risk-exaggerating) and represent the 95% upper-bound confidence limit of tumor induction likely to occur from a given dose (NRC, 1987). To calculate an oncogenic risk, the Q^* , expressed in units of excess tumor incidence/[mg pesticide exposure/(kg body weight \times day)], is multiplied by the estimated daily exposure [mg/(kg \times day)]. By contemporary convention, oncogenic risks below 10^{-6} (0.000001, or one per million) are typically defined as negligible risks (NRC, 1987).

To estimate dietary pesticide exposure, the EPA relies upon a computer-based system known as the dietary risk evaluation system (DRES) (Tomerlin and Engler, 1991). This system calculates typical food consumption rates for 22 distinct population groups based upon region, ethnicity, age, and gender based upon results of USDA Nationwide

Food Consumption Surveys and predicts dietary exposure to pesticides by multiplying pesticide residue levels by the food consumption estimates.

The most common calculation made by DRES is the theoretical maximum residue contribution, or TMRC. In calculating the TMRC, it is assumed that 100% of the crops that may be legally treated with a pesticide are in fact treated and that residues are always present at the tolerance levels. The TMRC, therefore, exists as a mathematical construct representing the maximum "legal" dietary exposure to pesticide residues.

For nononcogenic pesticides, as a general practice, the EPA has approved proposed tolerances if the TMRC resulting from existing uses of the pesticide and the new proposed uses is less than the ADI or RfD (Moore, 1987). On occasions in which the proposed uses may cause the ADI or RfD to be exceeded, the manufacturer of the pesticide may voluntarily cancel other existing uses of the pesticide to clear room for the proposed tolerance under the ADI or RfD ceiling. The decision to approve or disapprove pesticide tolerances based upon comparisons of the TMRC with the ADI or RfD is only a *practice* used by EPA and does not represent a prescribed *policy*. In some cases, the EPA has approved tolerances where the TMRC has exceeded the ADI when reliable data concerning the percentage of acres treated with the pesticide and/or actual residue data are incorporated into DRES and demonstrate that exposure appears to be below the ADI. It must be emphasized that the EPA, through FIFRA, ultimately reserves the right to grant or deny tolerances based upon its determination of both the risks *and the benefits* stemming from the use of the pesticide.

Based upon the previous discussion, it is clear that the *actual pesticide tolerances* are determined solely from the results of controlled residue studies and are *not* influenced by ADI or RfD values, which serve as regulatory sorting tools useful in the preliminary assessment of dietary risk. The misconception that tolerances are based upon these toxicological benchmarks is widely held among scientists and policymakers and serves to magnify the level of confusion regarding the health significance of pesticide tolerances.

In the case of oncogenic pesticides in food, the EPA in 1988 adopted a policy of de minimus, or negligible, risk (Sisco, 1991), with a negligible oncogenic risk defined as less than one cancer per million. As a matter of practice, the EPA will approve a tolerance petition if the risk posed by the pesticide at the TMRC, or at levels incorporating reliable actual pesticide use or residue data, is below the negligible risk cutoff. In the case of oncogenic pesticides that exceed a negligible risk, the EPA may still approve pesticide tolerances if the benefits from the use of the pesticide are deemed to outweigh the risks. An exception exists in the case of residues that concentrate in processed forms or are applied directly to processed forms. The pesticides in these cases are regulated as food additives and are therefore subject to the Delaney Clause of the FFDCFA, which prohibits the use of chemicals on food that have been shown to "induce cancer" in humans or animals (NRC, 1987). It is the EPA's new policy that if the oncogenic risks from these pesticides are greater than negligible, petitions for tolerances will be denied regardless of the potential benefits of the pesticides (Sisco, 1991).

ENFORCING PESTICIDE TOLERANCES

At the federal level, the responsibilities for monitoring and enforcement of tolerances for foods that enter interstate commerce are given to the United States Food and Drug

Administration (FDA) and the United States Department of Agriculture (USDA). The FDA is primarily involved in the monitoring of raw and processed agricultural products and feed, while the USDA is responsible for analyzing meat and poultry products. Both the FDA and the USDA monitor eggs and egg products, and the FDA also monitors milk, cheese, grains, and fish for pesticide residues. At the present time, plans are underway for significant expansion of USDA monitoring programs in terms of sampling rate and the variety of food items analyzed for pesticide residues.

Individual states may also be involved in pesticide residue monitoring. As of 1989, at least 38 states had residue monitoring programs, although programs vary considerably in terms of purpose, sampling rates, and comprehensiveness of pesticide coverage (Minyard *et al.*, 1989; Archibald and Winter, 1990). California currently has the largest state monitoring program and typically analyzes nearly 15,000 food samples annually for pesticide residues. Other states having significant monitoring programs include Florida, Texas, and New York.

Monitoring results from the FDA's "surveillance" program and California's "routine marketplace surveillance" program for the period of 1987 to 1990 are summarized in Table 2. The programs differ in their sampling strategies. The FDA program is biased toward sampling food items that may present the greatest potential for illegal residues (Reed *et al.*, 1987) while sampling in the California program is more random. The programs also differ in the scope of pesticides routinely analyzed for; the FDA uses multiresidue screening methods capable of detecting 253 pesticides and/or metabolites while the California methods can detect residues of slightly more than 100 pesticides. The origin of samples analyzed also differs. During 1987 to 1990, 56.5% of FDA's samples involved foreign foods while 17.5% of samples from all of California's programs during the same period represented foreign foods.

TABLE 2
SUMMARY OF FDA SURVEILLANCE^a AND CALIFORNIA DEPARTMENT OF FOOD AND AGRICULTURE
ROUTINE MARKETPLACE SURVEILLANCE PESTICIDE MONITORING RESULTS, 1987-1990^{b,c}

Year	Number of samples analyzed	Percentage nondetected	Percentage legal residues	Percentage over tolerance	Percentage no tolerance established	Percentage illegal
FDA surveillance						
1987	14,492	56.9	38.9	0.8	3.4	4.2
1988	18,114	61.2	35.2	0.6	3.1	3.7
1989	18,113	66.3	31.2	0.5	2.0	2.5
1990	19,146	63.0	34.2	N.A.	N.A.	2.8
California routine marketplace surveillance						
1987	7,010	79.8	18.8	0.3	1.2	1.5
1988	9,293	78.1	20.7	0.2	0.9	1.2
1989	9,403	77.9	21.3	0.2	0.5	0.7
1990	8,278	79.8	19.4	0.2	0.6	0.8

Note: N.A., data not available.

^a Data include compliance monitoring results for 1987 and 1988; compliance samples are generally taken as follow-ups of violative surveillance samples and typically show a much greater incidence of illegal residues.

^b Values may not add up to 100% due to round-off errors.

^c Sources: FDA, 1988, 1989, 1990, 1991; California Department of Food and Agriculture 1988, 1989, 1990, 1991.

As is illustrated in Table 2, the majority of samples analyzed from both programs were not found to contain any detectable residues, and violation rates were low. Most of the violations occurred when residues were detected that did not have established tolerances on the particular commodity rather than when residues exceeded tolerances. In California, for example, only 21.5% of the illegal residues detected in the routine marketplace surveillance program from 1987 to 1990 involved residues found in excess of tolerance.

Both the FDA and California monitoring programs have been criticized for their sampling rates (less than 1% of the food may be analyzed) and for the number of pesticides routinely analyzed for, since approximately 350 different pesticides may theoretically leave residues (United States General Accounting Office, 1986a, 1986b; California Assembly Office of Research, 1988). Both programs, however, also perform selective surveys to look for residues of pesticides that are not typically detected using the multiresidue screens; results from such surveys have indicated that residue findings for these pesticides are similar to findings determined for pesticides that are amenable to the multiresidue screens. In California, for example, a priority pesticide monitoring program has been in place to monitor for residues of pesticides that are not detected in the multiresidue screens from commodities to which the pesticides were known to be applied. From 1987 to 1990, 7436 samples were analyzed in this program. Of these, 88.15% did not result in detectable residues even though the pesticides were applied. Only two samples (0.03%) showed residues in excess of tolerances while the remaining 11.82% of the samples had residues below tolerances. Results from FDA-focused surveys have been similar (Lombardo, 1989).

While much attention has centered upon the acknowledged limitations of existing government monitoring programs, it appears that little effort has been made to explain and interpret the results of the programs. As was demonstrated in Table 2, residue monitoring data for the past several years have consistently shown that residue levels rarely approach or exceed tolerance levels and that residues have not been detected in the majority of samples analyzed.

These results can be explained primarily through consideration of two factors. The principal factor is the method by which tolerances are established in the first place. Since tolerances are set to accommodate the maximum residues expected under the most severe application conditions and are therefore expected to be much higher than average residues resulting from normal use of the pesticides, one would typically expect residue findings to be well below tolerance levels. The fact that this assumption is supported by the results of regulatory monitoring programs indicates that typical pesticide applications appear to be made in accordance with legal requirements, since overtolerance residues would be anticipated only if serious errors were made during pesticide application.

The second factor explaining the results of monitoring programs relates to actual pesticide use. Although California now requires that all agricultural uses of pesticides be reported, obtaining accurate national use data is still difficult (Gianessi, 1991). Data that do exist, however, indicate that pesticides are frequently not used on commodities for which they are registered. As an example, Chaisson *et al.* (1987) reported on the pesticide use of California tomato growers during 1986. Of the 54 insecticides that had tolerances established on tomatoes, the maximum number used by any tomato grower was five and no applications of the 54 insecticides were made by 31% of the tomato growers. A total of 26% of the growers used a single insecticide during 1986.

while 26% used two different insecticides, 12% used three, and 4% used four. Similar results were reported for fungicide and herbicide use.

In combination, consideration of actual pesticide use and of the procedures for tolerance establishment helps explain the relatively low levels of pesticide residues reported by regulatory agencies and enables predictions to be made of the impact of changes in monitoring programs upon subsequent residue findings. If monitoring results are primarily governed by these factors, it appears unlikely that increases in sampling rates or in the number of pesticides monitored would have much of an effect upon the residue profiles that are commonly observed.

HEALTH SIGNIFICANCE OF LEGAL RESIDUES

Since pesticide tolerances are approved by the EPA only after consideration of comprehensive toxicology data and estimates of human exposure to the pesticides, it seems logical to consider exposures to "legal" levels of residues as "safe" exposures, as has been reported by regulatory officials (Trichilo and Schmitt, 1989). The concept of safety, however, is subject to a variety of definitions and may include nonscientific factors determined by society as well as scientific factors.

From a toxicological perspective, a safe level of exposure can be defined as exposure below the ADI or, in the case of an oncogenic chemical, exposure that does not cause the oncogenic risk to exceed a negligible level. If one considers this definition of safety, it may be argued that exposure to some legal residues may, at least on a theoretical basis, represent exposure to "unsafe" levels.

In the case of nononcogenic pesticides, it seems appropriate to consider legal residues as safe residues provided that the TMRC is below the ADI: this finding is typically required before EPA will approve tolerance petitions. Several exceptions to this rule exist, however. It has been reported that the TMRCs for 14 pesticides—carbofuran, chlorpyrifos, demeton, dioxathion, disulfoton, diuron, endosulfan, ethion, ethoprop, lindane, MCPA, methidathion, monocrotophos, and phorate—have exceeded ADIs and that this finding did not prevent the EPA from approving additional food tolerances for these pesticides (Mott, 1986; California Assembly Office of Research, 1988). The EPA has acknowledged that some TMRCs do exceed ADIs, particularly in cases where the ADI is "provisional" and reflects a compensatory margin of safety (generally 1000 instead of 100) due to toxicology data deficiencies or when the ADI has been changed as a result of action by the EPA's ADI review committee (Moore, 1987). At any rate, in the absence of additional data, statements reflecting the "safety" of legal residues of these pesticides are difficult to substantiate.

A similar situation exists for oncogenic pesticides. In 1987, the NRC performed calculations demonstrating that exposure to TMRC levels for 23 out of 28 pesticides for which Q^* s were available led to oncogenic risks exceeding the negligible risk standard of one cancer per million (NRC, 1987). As has been described previously, existing EPA policy allows for the approval of pesticide tolerances even if the oncogenic risks are not negligible, except for pesticides subject to food additive tolerances, since FIFRA statutes allow for consideration of both pesticide risks and pesticide benefits when the provisions of the Delaney Clause of FFDCA do not apply. (Examples of this policy are given in Table 3 and are discussed below.) Theoretical exposure to legal residues of some oncogenic pesticides, therefore, may pose greater than negligible risks. This

illustrates, as was the case with pesticides for which the TMRC exceeded the ADI, that safe residues and legal residues are not interchangeable.

HEALTH SIGNIFICANCE OF ILLEGAL RESIDUES

If one considers pesticide tolerances to be safety standards, then it would appear to be logical to consider "illegal" residues as "unsafe" residues. This conclusion is often emphasized through descriptions of the regulatory monitoring programs which serve to provide "consumer protection" from illegal residues (Reed *et al.*, 1987; Lombardo, 1989) as well as from criticisms of existing programs with regard to their abilities to "protect the public from illegal residues" (United States General Accounting Office, 1986a; California Assembly Office of Research, 1988).

In some cases, human poisoning has occurred as a result of exposure to illegal pesticide residues in food (Ferrer and Cabral, 1989). As an example, in 1985, illegal application of the insecticide aldicarb to California watermelons, a commodity for which no aldicarb tolerance exists, resulted in hundreds of cases of cholinergic poisoning throughout the western United States (Centers for Disease Control, 1986; Goldman *et al.*, 1990). Most poisoning cases from illegal pesticide residues have involved acute toxicity from large exposures to highly toxic pesticides originating from pesticide misuse or inadvertent addition of pesticides to food (Ferrer and Cabral, 1989).

While these cases illustrate that illegal residues may contribute to human poisoning, such cases are exceedingly rare and do not appear to be typical of the vast majority of illegal residue cases. Additionally, most current attention with regard to dietary exposure to residues in food focuses upon the potential chronic health effects from long-term low-level exposure to pesticides rather than from acute exposures.

By definition, an illegal residue would constitute an unsafe residue only if exposure to the residue caused total dietary exposure to the pesticide to exceed the ADI or, in the case of an oncogenic pesticide, led to a nonnegligible oncogenic risk. In addition, since all oncogenic risk estimates and most ADI values assume continuous lifetime (70-year) exposure, temporary exposures to illegal residues meeting this definition of unsafe may still not be of toxicological significance when considered over an entire human lifetime.

As an aid in the investigation of the health significance of illegal pesticide residues, a computer search of *Federal Register* citations for pesticide tolerances approved by EPA from January 1988 to August 1991 was performed. Data from these citations were used to compile Table 3 which compares the EPA's TMRC calculations with ADI values for 35 pesticides identified by the search.

It is evident that for most of the pesticides listed in Table 3, the TMRCs, representing the hypothetical maximum legal exposures, are considerably lower than the ADIs, indicating the apparent safety of legal residues in these cases. TMRCs accounting for less than 5% of the ADIs existed for 23 of the 35 pesticides, while TMRCs between 5 and 10% of ADIs were noted for 4 pesticides, and TMRCs between 10 and 50% of ADIs were encountered for 6 pesticides.

To place the health significance of illegal residues in perspective, consider the pesticide fluridone, which at the date of the final ruling shown in Table 3 had 50 separate tolerances established for food items. Assuming that fluridone residues on all 50 foods were always present at the tolerance levels, the calculated TMRC exposure still rep-

TABLE 3
COMPARISON OF THEORETICAL MAXIMUM RESIDUE CONTRIBUTIONS (TMRCs)
WITH ACCEPTABLE DAILY INTAKES (ADIs) FOR SELECTED PESTICIDES

Pesticide	Date of final rule	Federal Register reference	TMRC ($\mu\text{g/kg/day}$)	ADI ($\mu\text{g/kg/day}$)	% ADI
Avermectin	05/31/89	54,23,209	0.053	13 ^a	13.3
Bifenthrin ^b	08/15/88	53,30,676	0.45	15	3.0
Chlorimuron ethyl	06/29/89	54,27,349	0.033	13	<0.1
Clofentezine ^c	06/12/91	56,26,911	0.59	13	4.5
Clopyralid	08/01/90	55,31,182	8.1	500	16.2
Cyfluthrin	01/25/88	53,1,923	0.26	25	1.0
Cyhalothrin	05/24/88	53,18,558	0.13	5	2.6
Cypermethrin	10/05/89	54,41,098	2.8	10	2.8
Express ^c	08/02/89	54,31,830	0.073	6.3	1.2
Fenoxaprop-ethyl	08/28/91	56,42,530	0.11	2.5	4.4
Fluazifop-butyl	06/29/89	54,27,348	2.1	10	2.1
Fluridone	07/20/90	55,29,828	6.9	80	8.6
Fluvalinate	04/18/90	55,14,421	0.16	10	1.6
Fosetyl Al ^c	04/04/90	55,12,483	1.5	3000	<0.1
Glyphosate	11/20/90	54,47,980	9.9	100	9.9
Hexythiazox ^d	04/26/89	54,17,947	0.037	25	0.1
Imazamethabenz	04/20/88	53,12,943	1.5	62.5	2.4
Imazethapyr	05/22/91	56,23,520	0.042	250	<0.1
Iprodione	01/29/90	55,2,845	47.8	40	119.5
Lactofen ^e	06/14/90	55,24,084	0.018	2 ^f	0.9
Metalaxyl	01/23/91	56,2,440	10.4	60	17.3
Methiocarb	03/22/89	54,11,705	3.6	12.5 ^g	28.8
Metolachlor ^h	11/27/89	54,36,568	1.3	150	0.9
Metsulfuron	06/21/89	54,21,220	0.11	13	0.8
Metsulfuron methyl	03/21/90	55,10,456	0.82	250	0.3
Nicosulfuron	07/12/90	55,28,619	0.033	1250	<0.1
Oxyfluorfen	01/06/88	53,243	0.71	3	23.7
Primisulfuron methyl	05/25/90	55,21,547	0.57	6 ^a	9.5
Propiconazole ⁱ	07/01/91	56,29,900	1.1	13	8.5
Quisalofof-ethyl	06/22/88	53,23,391	0.22	9	2.4
Sethoxydim	03/20/91	56,11,677	32.0	90	35.6
Tefluthrin	02/01/89	54,5,080	0.01	0.75 ^j	1.3
Thiobencarb	01/23/91	56,2,439	1.3	10	1.3
Triadimenol	08/02/89	54,31,833	0.45	38 ^k	1.2
Vinclozolin	04/06/88	53,11,274	13.0	25	52.0

^a Calculation of ADI used 300-fold uncertainty factor.

^b Class C carcinogen at time of ruling; cancer risk at TMRC = 2.4×10^{-5} .

^c Class C carcinogen at time of ruling; quantitative risk assessment not performed.

^d Class C carcinogen at time of ruling; cancer risk at TMRC = 1.4×10^{-6} .

^e Class B2 carcinogen at time of ruling; cancer risk at TMRC = 3.2×10^{-6} .

^f Calculation of ADI used 1000-fold uncertainty factor from lowest effect level.

^g Calculation of ADI used 10-fold uncertainty factor.

^h Class C carcinogen at time of ruling; cancer risk at TMRC = 2.6×10^{-4} .

ⁱ Class C carcinogen at time of ruling; cancer risk at TMRC = 8.7×10^{-5} .

^j Provisional ADI; 1000-fold uncertainty factor used.

^k Provisional ADI.

resents only 8.6% of the ADI. For exposures to exceed the ADI, *all* residues of fluridone on *all* 50 foods would *always* have to exceed the tolerance by an average of 12 times. Given the relationship between actual residue levels and tolerance levels, such a scenario is difficult to envision. In the case of individual *illegal* fluridone residues, even if one assumes a worst-case scenario, the contribution of such residues to overall dietary exposure would be minimal and a large margin of safety between actual exposure and the ADI would still exist. While such illegal residues are indicative of pesticide misuse and/or inadvertent contamination of nonregistered commodities, they do *not*, ordinarily, represent unsafe residues.

In only two cases were the TMRCs found to represent more than 50% of the ADIs. The TMRC for vinclozolin, which assumes residues at tolerance levels for each of the 12 food items for which tolerances exist, was 52% of its ADI. Market basket survey data obtained from the FDA's 1990 Total Diet Study estimated a maximum exposure of 0.0015 $\mu\text{g/kg/day}$, representing only 0.006% of the ADI of 25 $\mu\text{g/kg/day}$ (FDA, 1991). Illegal vinclozolin residues, therefore, would not appear to have any toxicological significance, even though the relationship between its TMRC and the ADI was relatively high in comparison with other pesticides.

In the case of iprodione, the TMRC, assuming residues at tolerance for all 65 registered foods, was 119.5% of the ADI. The EPA uses a much lower ADI for iprodione (40 $\mu\text{g/kg/day}$) than the ADI value of 300 $\mu\text{g/kg/day}$ established by the United Nations Food and Agriculture Organization/World Health Organization (FDA, 1991); the TMRC calculation for iprodione represents 15.9% of this higher ADI value. At any rate, a more realistic exposure estimate for iprodione, from the FDA 1990 Total Diet Study, is 0.0011 $\mu\text{g/kg/day}$, or 0.0028% of the EPA's ADI of 40 $\mu\text{g/kg/day}$ (FDA, 1991). Based on this finding, it is highly unlikely that illegal iprodione residues would be of any toxicological significance, even though the iprodione TMRC exceeds the EPA's ADI.

Table 3 also shows that 5 of the 35 pesticides selected were considered by the EPA to be oncogenic and suitable for quantitative oncogenic risk assessment at the time of the final rulings. Assuming exposures at the TMRC levels, oncogenic risk estimates exceeded the negligible risk standard by factors of 1.4, 2.6, 3.2, 24, and 87. It is quite likely that oncogenic risks for these pesticides, using more realistic exposure estimates, would be below the negligible risk standard, as related studies have indicated that the TMRCs may exaggerate exposures to oncogenic pesticides by factors of 200 to 100,000 (Archibald and Winter, 1990). It is also likely that illegal residues for these pesticides would not cause the negligible risk level to be exceeded, again illustrating that illegal and unsafe residues are not synonymous.

DISCUSSION

As has been demonstrated, the practices used in the establishment of pesticide tolerances are complicated and may serve to cast confusion as to the relationship of pesticide tolerances and safety standards. Generally speaking, tolerances are set to accommodate the maximum residues found during controlled field studies. The tolerances are established independently of health criteria such as ADIs, RfDs, and Q^* s, although the EPA normally considers both the health criteria and the potential benefits of the pesticide's use before deciding whether to approve or deny a tolerance petition.

It is concluded that pesticide tolerances have little or no relevance as safety standards. This conclusion is based upon the findings that *theoretical* exposures to legal levels of pesticides in the diet may pose greater than negligible risks, while exposures to most illegal residues are of no apparent toxicological significance. The logical and widely held perceptions of legal residues as safe residues and illegal residues as unsafe residues are not supported by scientific evidence.

While pesticide tolerances are not useful as safety standards, they serve a valuable role as enforcement tools. Residues originating from pesticide applications made according to legal directions should not exceed tolerance levels as a result of the method by which the tolerances are established. Only in the case of pesticide misuse is it anticipated that residue levels would exceed tolerances. Additionally, findings of illegal residues on commodities for which the pesticide is not registered also indicate pesticide misuse and/or inadvertent contamination due to drift, soil uptake, or other environmental factors. Pesticide tolerances, therefore, serve vital functions as indicators of the proper application of pesticides. Tolerance enforcement programs provide economic disincentives that discourage pesticide misuse, regulate international trade, and emphasize compliance with regulations. Historical data indicate that the vast majority of food analyzed for pesticide residues, both domestic and imported, is in compliance with established tolerances, suggesting that pesticide misapplication is not a common practice.

The popular misperception that pesticide tolerances serve as safety standards is evident in recent and current legislative bills designed to increase the safety of the food supply. A common theme involves setting tolerances low enough that the TMRC will not exceed the ADI, and, in the case of oncogenic pesticides, exposure at the TMRC level will pose no more than a negligible risk.

While the effect of such an approach upon agricultural practices is uncertain, it is doubtful that lowering the tolerances will have much of an effect upon human health. This practice would lower the TMRC, but since typical exposure is already orders of magnitude below the TMRC, the human health benefits may be insignificant. As an example, consider the effect of reducing *all* pesticide tolerances by a factor of 2. This action would serve to *halve* all pesticide TMRCs and would *theoretically* lower pesticide risks by a factor of 2. In actuality, however, assuming that this action did not affect pesticide use practices, the effects on human health would still be minimal. Using data from California's 1987 routine marketplace surveillance program as an example, reducing all tolerances by a factor of 2 would reduce the percentage of samples found to be in compliance with pesticide tolerances from 98.5 to 97.5% (California Department of Food and Agriculture, 1988). Such an action would therefore have little effect upon typical dietary exposure to pesticides. The process of reducing pesticide tolerances may, however, produce dramatic effects upon domestic and international agricultural practices and may lead to barriers to international trade that are not justified by health data.

Much additional concern has focused upon the adequacy of government monitoring programs to provide consumer protection. Existing monitoring programs are costly and are therefore limited in their sampling rates and individual pesticide detection capabilities. Programs have also been criticized for their ability to seize foods containing illegal residues once the foods have entered the channels of commerce (United States General Accounting Office, 1986a). While calls for significant expansion of these programs, at a considerable expense, are often heard, it is important to consider the effects

of program expansion upon human health. Since the vast majority of illegal residues are of no toxicological significance, the increased capabilities to detect illegal residues and to remove the foods from commerce may be of little health benefit.

Finally, the appropriateness of the use of the TMRC as an indicator of exposure requires discussion. While the TMRC does serve a useful purpose by providing the EPA with "a useful sorting tool for determining regulatory priorities" (Moore, 1987), this mathematical construct has often been improperly substituted as an indicator of actual pesticide exposure. This was particularly evident in the widespread dissemination of the findings of the 1987 NRC report, for which the TMRC was used to determine theoretical oncogenic risks for 28 different pesticides (NRC, 1987). Although a subsequent study has illustrated the degree by which the TMRC calculations may overestimate exposure (Archibald and Winter, 1990), numerous publications (i.e., Mott and Snyder, 1988; Kilham, 1991) have presented the NRC data as definitive, with the conclusion that over 1,000,000 cases of cancer will occur as a result of exposure to cancer-causing pesticides in food.

CONCLUSION

While numerous scientific barriers exist which compromise the accuracy of estimations of the dietary risks posed by pesticides, it is important that risk assessments be based upon the best available scientific data, that efforts are continually made to upgrade the scientific data base, and that the health significance of pesticide tolerances is understood. It is apparent that the common misperception of pesticide tolerances as safety standards may potentially be magnified into food safety legislation of questionable benefit to human health.

REFERENCES

- ARCHIBALD, S. O., AND WINTER, C. K. (1990). Pesticides in food: Assessing the risks. In *Chemicals in the Human Food Chain* (C. K. Winter, J. N. Seiber, and C. F. Nuckton, Eds.), pp. 1-50. Van Nostrand-Reinhold, New York.
- California Assembly Office of Research (1988). *The Invisible Diet: Gaps in California's Pesticide Residue Detection Program* (P. Price, Ed.). California Assembly Office of Research, Sacramento, CA.
- California Department of Food and Agriculture (1988). *Pesticide Residue Annual Report for 1987*. Pesticide Enforcement Branch, Sacramento, CA.
- California Department of Food and Agriculture (1989). *Pesticide Residue Annual Report for 1988*. Pesticide Enforcement Branch, Sacramento, CA.
- California Department of Food and Agriculture (1990). *Pesticide Residue Annual Report for 1989*. Pesticide Enforcement Branch, Sacramento, CA.
- California Department of Food and Agriculture (1991). *Pesticide Residue Annual Report for 1990*. Pesticide Enforcement Branch, Sacramento, CA.
- Centers for Disease Control (1986). Aldicarb food poisoning from contaminated melons—California. *J. Am. Med. Assoc.* 256, 175-176.
- CHAISSON, C. F., PETERSEN, B., AND EICKHOFF, J. C. (1987). *Pesticides in Our Food: Facts, Issues, Debates and Perceptions*. Technical Assessment Systems, Washington, DC.
- FERRER, A., AND CABRAL, J. P. R. (1989). Epidemics due to pesticide contamination of food. *Food Addit. Contam.* 6, S95-S98.
- FDA (1988). Residues in foods—1987. *J. Assoc. Off. Anal. Chem.* 71, 156A-174A.
- FDA (1989). Residues in foods—1988. *J. Assoc. Off. Anal. Chem.* 72, 133A-152A.
- FDA (1990). Residues in foods—1989. *J. Assoc. Off. Anal. Chem.* 73, 127A-146A.

- FDA (1991). Residues in foods—1990. *J. Assoc. Off. Anal. Chem.* 74, 121A–141A.
- GIANESSI, L. P. (1991). Use of pesticides in the United States. In *Pesticide Residues and Food Safety: A Harvest of Viewpoints* (B. G. Tweedy, H. J. Dishburger, L. G. Ballantine, and J. McCarthy, Eds.), pp. 24–30. Am. Chem. Soc., Washington, DC.
- GOLDMAN, L. R., BELLER, M., AND JACKSON, R. J. (1990). Aldicarb food poisonings in California, 1985–1988: Toxicity estimates for humans. *Arch. Environ. Health* 45, 141–147.
- KILHAM, C. S. (1991). *The Bread and Circus Whole Food Bible*. p. 12. Addison-Wesley, New York.
- LOMBARDO, P. (1989). The FDA pesticides program: Goals and new approaches. *J. Assoc. Off. Anal. Chem.* 72, 518–520.
- MCCARTHY, J. F. (1991). Average residues vs. tolerances: An overview of industry studies. In *Pesticide Residues and Food Safety: A Harvest of Viewpoints* (B. G. Tweedy, H. J. Dishburger, L. G. Ballantine, and J. McCarthy, Eds.), pp. 182–191. Am. Chem. Soc., Washington, DC.
- MINYARD, J. P., JR., ROBERTS, W. E., AND W. Y. COBB (1989). State programs for pesticide residues in foods. *J. Assoc. Off. Anal. Chem.* 72, 525–533.
- MOORE, J. A. (1987). Statement before the Committee on Agriculture, Nutrition, and Forestry, U.S. Senate. In *Proceedings, Senate Hearing 100-394, Part I*. United States Congress, Washington, DC (May 20, 1987).
- MOTT, L. (1986). *Pesticide Reregistration: An Evaluation of EPA's Progress*. p. 47. Natural Resources Defense Council, San Francisco.
- MOTT, L., AND SNYDER, K. (1988). *Pesticide Alert: A Guide to Pesticides in Fruits and Vegetables*. p. 2. Sierra Club, San Francisco.
- NRC (1987). *Regulating Pesticides in Food: The Delaney Paradox*. Natl. Acad. Press, Washington, DC.
- National Resources Defense Council (NRDC) (1989). *Intolerable Risk: Pesticides in Our Children's Food*. Natural Resources Defense Council, Washington, DC.
- Opinion Research Corporation (1990). *Trends, Consumer Attitudes, and the Supermarket, 1990*. Food Marketing Institute, Washington, DC.
- REED, D. V., LOMBARDO, P., WESSEL, J. R., BURKE, J. A., AND MCMAHON, B. (1987). The FDA pesticides monitoring program. *J. Assoc. Off. Anal. Chem.* 70, 591–595.
- SISCO, D. (1991). Regulation of pesticides in food: Addressing the Delaney paradox policy statement. In *Pesticide Residues and Food Safety: Aspects of a Changing Structure*. pp. 5–16. United States Department of Agriculture, Economic Research Service, Washington, DC.
- TOMERLIN, J. R., AND ENGLER, R. (1991). Estimation of dietary exposure to pesticides using the dietary risk evaluation system. In *Pesticide Residues and Food Safety: A Harvest of Viewpoints* (B. G. Tweedy, H. J. Dishburger, L. G. Ballantine, and J. McCarthy, Eds.), pp. 192–201. Am. Chem. Soc., Washington, DC.
- TRICHLO, C. L., AND SCHMITT, R. D. (1989). Tolerance setting process in the U.S. Environmental Protection Agency. *J. Assoc. Off. Anal. Chem.* 72, 536–538.
- United States General Accounting Office (1986a). *Pesticides: Need to Enhance FDA's Ability to Protect the Public from Illegal Residues*. GAO/RCED-87-7. U.S. Govt. Printing Office, Washington, DC.
- United States General Accounting Office (1986b). *Pesticides: Better Sampling and Enforcement Needed on Imported Food*. GAO/RCED-86-219. U.S. Govt. Printing Office, Washington, DC.

The Benefits of Pesticides in U.S. Crop Production

Testimony by

Leonard P. Gianessi

Fellow

Resources for the Future

July 14, 1993

**Before the Subcommittee on Department Operations and Nutrition, House
Committee on Agriculture**

My name is Leonard Gianessi. I am a Fellow at Resources for the Future, a private non-profit research organization in Washington, D.C. My statement is my own and does not represent the position of Resources for the Future. I have worked for the past seven years collecting information and data on the uses of pesticides in U.S. agriculture. I've prepared reports for USEPA, USDA, FDA, NOAA and USGS outlining the uses of pesticides. I've worked closely with plant pathologists, entomologists and weed scientists across the country to assemble this information. Today I will summarize what I have learned about why U.S. farmers make extensive use of synthetic chemical pesticides.

Synthetic chemical pesticides were introduced into U.S. agriculture in the 1940's and quickly gained widespread use because of the benefits that they provided. Synthetic chemicals replaced many labor intensive methods of controlling pests. For example, in the early 1900's it had been common practice to hand hoe weeds out of cotton fields. The use of synthetic chemicals to control weeds eliminated the need for millions of hours of drudgery in cotton fields with a hoe to dig weeds out.

Synthetic chemicals replaced some very harsh natural chemicals that had been used to control pests. From 1900 to 1950 the nation's apple growers sprayed lead arsenate and lime sulfur on their trees to control diseases and insects. These natural chemicals were damaging to the trees as well as damaging to the pests. When apple growers switched to synthetic chemicals, the per tree yield in states like New York and Michigan went up by 100% because the synthetic chemicals were less damaging to the trees than the harsh natural chemicals had been.

Synthetic chemicals have led to many instances of dramatic increases in crop yields in the country. For example, field corn yields have gone up dramatically in the past fifty years. One major reason for the increase in corn yields has been the practice of planting more corn plants per acre. More corn plants per acre translates directly to higher yields. One reason that corn growers have been able to increase the number of plants per acre has been the use of synthetic herbicides for weed control. Before the use of synthetic herbicides, it had been the practice to plant individual corn plants far enough apart so that cultivators could pass close by each corn plant on all four sides to cultivate the weeds out. With synthetic chemicals that could be sprayed at the bottom of the corn plants to control weeds, it was possible to plant corn in rows with the plants close together. It was no longer necessary to leave all that room between individual corn plants in order to cultivate the weeds out. Synthetic herbicides could be used instead.

There are numerous instances of synthetic chemicals providing control of diseases and insects that had been limiting crop yields. For example, in Maine potato fields prior to 1949, growers had been using natural fungicides to control diseases of potatoes. In the year 1949 when synthetic fungicides were introduced and widely used, per acre potato yields in Maine increased by 33% because of superior disease control. In California strawberry fields, the utilization of fumigation with chemicals to control soil diseases beginning in the early 1960's is largely credited with tripling per acre yields of strawberries.

Synthetic chemicals have made it possible to expand the acreage of crops in regions where pests had limited their potential. For example, in the past several years there has been a dramatic

increase in corn acreage in Southeastern states such as Mississippi, Georgia and Alabama. One of the key reasons Southeastern farmers are expanding corn plantings is the availability of new herbicides which for the first time offer economical control of very hard-to-control weeds. Why is increased corn plantings in Southeastern states important? One reason is that economical corn plantings may lead to more diverse crop rotations. Corn is a good rotation crop with peanuts, for example.

The nations farmers use about 200 different chemical active ingredients in pesticide products to control pests in the nation's food and fiber production. These chemicals are targeted at a vast array of pests. There are about 410 weed species, 34 mite species, 137 diseases, 22 nematode species, and 304 insect species that are injurious to crops grown in this country. U.S. growers currently use about 800 million pounds of pesticide active ingredients per year. 500 million pounds are used as herbicides to control weeds, 150 million pounds are used to control insect pests and 65 million pounds are fungicides to control diseases. This use is spread out in all areas of the country in vastly different growing regions in 100 or so important agronomic crops and targeted against hundreds of different pests. So there are literally thousands of specific combinations of pest, pesticide, crop and region.

Based on the studies that I have conducted, I can offer the following four general statements as to why U.S. farmers use synthetic chemicals: (1) Farmers use synthetic chemicals because they are cost-effective in controlling pests that would otherwise significantly damage crop yields, interfere with harvesting crops or lower the quality of crops; (2) farmers select synthetic chemicals because non-chemical alternatives are either non-existent, cost more or work less well in preventing damage due to pests; (3) farmers use synthetic pesticides because these chemicals reduce the risk of crop losses due to unusual weather conditions or unusual pest outbreaks; and (4) farmers use synthetic pesticides because their usage is efficient given the way that U.S. agriculture is currently organized.

Crop yields would decline if U.S. farmers did not use synthetic chemical pesticides because non-chemical alternatives are either non-existent or less effective in the control of pests. In order to estimate the magnitude of the yield reductions that would result if farmers did not use synthetic chemicals, several surveys of the nations crop protection scientists have been undertaken. In these surveys, the crop protection scientists are asked for estimates of the change in yields if farmers didn't use synthetic chemical pesticides and instead used other available methods of pest control. The results aggregated for the nation from a study conducted by Texas A&M University are summarized below:

	% Yield Reduction	
	No herbicides	No insecticide or fungicides
Corn	-30	-5
Soybeans	-35	-3
Wheat	-23	-4
Barley	-28	-3
Cotton	-17	-26

Rice	-53	-16
Peanuts	-29	-66

In a study by GRC Economics, the yield losses resulting if synthetic fungicides were not used are estimated as follows.

% Yield Reduction with no synthetic fungicides

Apples	-40
Grapes	-33
Peaches	-49
Potatoes	-23
Lettuce	-15
Onions	-18
Carrots	-14
Citrus	-3

Critics have attacked studies such as these for being too pessimistic on yields. However, reports of actual operating organic farms support the results of the surveys of crop protection scientists. In a comparison of yields in conventional and organic farms in Ohio in 1990, it was determined that organic growers incurred yield losses as follows: corn (-30%), soybeans (-17%), wheat (-27%) and oats (-20%). In the NAS report *Alternative Agriculture*, an organic rice operation in California is described. This grower incurred yield losses of 50% on the organic rice acres in comparison with the conventionally grown rice.

In a recent article in the *New York Times* (June 20, 1993) organic cotton production in California is described: yields are 20% lower and production costs are three to four times higher than conventionally produced cotton.

Why would yield losses caused by diseases be so much higher without synthetic fungicides for fruit and vegetable crops like lettuce and onions than for corn and soybeans? The answer is that increasing the levels of genetic resistance to pathogens in major field crops has been a priority in major crop breeding programs in this country for many years. As a result, diseases are not generally a problem in corn fields and fungicides don't have to be used. As a result, the loss of synthetic fungicides would not have a great impact on corn yields. High levels of disease resistance is not present in most desirable fruit and vegetable cultivars. Since most fruit and vegetable cultivars are susceptible to diseases, synthetic fungicides are used to control the diseases.

Some diseases can be managed with natural substances such as sulfur and copper. For example, the major diseases of citrus can be managed with copper. As a result, the loss of synthetic fungicides would have only a minimal impact on citrus yields. However, sulfur and copper would control only certain diseases of apples. Apple diseases not controlled by sulfur and copper include bitter rot, white rot and black rot. These rots would probably occur in 25-50% of

the apple orchards in mid-Atlantic states where high rainfall and high humidity in the summer cause outbreaks that are currently controlled with synthetic chemicals.

Why would yield losses occur without herbicides? The major alternative to the use of herbicides for weed control is cultivation. While cultivation can be used (and is extensively used) to cultivate weeds from between the rows of cotton and corn plants, cultivators can't easily remove weeds from within the rows of plants. The uncontrolled weeds in the row would then lead to yield loss.

Crop production costs would increase if U.S. farmers did not use synthetic chemicals because many non-chemical alternatives are more expensive than synthetic chemicals. For weed control, some crops with high value per acre can be grown without synthetic herbicides through the use of hand labor to pull weeds or through the use of plastic mulch to smother weeds. However, the use of hand labor or plastic would cost growers about \$300/acre while synthetic chemicals currently cost fruit and vegetable growers \$15-20/acre. Certain insects can be controlled with artificial pheromones that result in mating disruption and keep insect populations low. However, these pheromones are generally more expensive than the use of synthetic chemicals. For example, in New York, researchers have released an artificial pheromone that controls the grape berry moth. The cost of the pheromone technology is \$65/acre to control this one pest. By contrast synthetic insecticides can be used at \$17/acre to control 2-3 major insect pests of grapes.

Generally, non-chemical alternatives for insect and disease control are less effective in controlling pests than are synthetic chemicals. Thus, to achieve equal control over the course of a season, the non-chemical alternatives have to be used more frequently and at higher costs. For example, in Northeastern apple orchards the costs of pesticides for an organic apple orchard is about \$248/acre while for standard conventional apple production the cost is \$95/acre. The conventional apple grower is estimated to apply 26 lbs/acre of pesticides while the organic grower has to use 101 lbs/acre of organically approved natural compounds.

Synthetic chemicals significantly reduce the risks of producing crops in the U.S. As noted above, a major non-chemical alternative for weed control is timely cultivation of crop fields. However, cultivation with a tractor is sometimes not possible due to wet or muddy field conditions. In order to reduce this risk, many farmers apply herbicides at planting or pre-plant for season-long weed control. Farmers who try to exclusively rely on tillage operations sometimes find it impossible to get into the field to cultivate weeds and, as a result, can face the loss of their crop. The NAS report *Alternative Agriculture* describes a Pennsylvania farmer who decided to use rotary hoes for weed control in soybean fields. The NAS report describes that when it was time for cultivation, the field was too wet, and the crop was overwhelmed by weeds. It's not clear that the farmer harvested any soybeans that year.

Synthetic pesticides have made it possible for growers to respond in emergency situations due to unusual weather and pest problems. Soybean growers in the Midwest generally do not require insecticide use. During a normal year, only about 1% of Illinois soybean acres are treated with insecticides. However, 1988 was an exceptional drought year in Illinois. Certain pests thrive

during drought and their populations increased dramatically. Illinois growers treated 40% of their soybean acres with insecticides in 1988. The synthetic chemicals made it possible to handle this emergency situation.

Tobacco growers in the U.S. had stopped using fungicides for disease control in the 1950's and, thus, were unprepared in 1979 as an epidemic of blue mold attacked tobacco. The lost production in 1979 totalled \$250 million. Because of the uncertainty of the development of epidemics, tobacco growers currently use fungicides at planting for season long control of possible outbreaks.

Sugarbeet growers typically apply an at-planting preventative soil insecticide which costs approximately \$20/acre. One major pest is the sugarbeet root maggot which can fly up to five miles to find a sugarbeet field. Producers don't want to risk losing a \$1200 per acre crop because they didn't apply a preventative control.

The use of synthetic chemicals increases the efficiency of U.S. agriculture. The size of U.S. farms has increased dramatically in the past few decades. A single farm manager may be responsible for a thousand acres of soybeans or corn. Season long weed control can be accomplished through the application of a herbicide to the ground when the corn or soybeans are planted. Once again, if the grower were to adopt a strategy of waiting until the weeds come up to cultivate them, it simply would not be possible for a single person to cover a thousand acres in the one or two days that are the critical period for weed removal. So given the large size of many U.S. farms, synthetic chemicals allow for efficient weed control operation.

On the other hand, many farm operators have full-time jobs off-the-farm. In Iowa, 27% of the persons identified as the farm operator, the key person on the farm, have full-time jobs off the farm. That's pretty efficient agriculture. What these farmers do is, once again, apply herbicides at planting for season long weed control. There is no real need to worry about day-to-day weed conditions due to the effectiveness of modern synthetic herbicides.

One other efficiency gained from the use of synthetic chemicals is to lengthen the season for food processing plants. For example, diseases in processing tomatoes in California are rarely a problem in the summer months. However, for tomatoes that are harvested in September, high humidity may lead to disease outbreaks and necessitate chemical usage. By producing tomatoes for a September harvest, the processing operation becomes more efficient. Overwintering spinach in New Jersey allows for early operation of processing facilities. Unfortunately, overwintering spinach is plagued with weed problems that can be removed with chemical herbicides. In Wisconsin green pea fields, weeds aren't usually a problem until later in the season. Once again, the efficient operation of processing facilities leads to planting crops in some cases when pest problems are higher. Synthetic chemicals have made it possible to extend the processing season in these cases.

The NAS report *Pesticides in the Diet of Infants and Children* includes several case studies of the risks of specific pesticide active ingredients. Benomyl and aldicarb are two of the

pesticides described in the NAS report. A brief description of some of the benefits of these products follows.

Aldicarb is an insecticide and nematocide - it controls certain insect and nematode species. The NAS report includes a case study of aldicarb risks on potatoes and correctly points out that aldicarb's use for potatoes was withdrawn in 1990. However, potato farmers have been writing to EPA and their legislators to urge that potato uses be restored to the aldicarb label. These potato farmers cite several negative changes that have occurred since aldicarb's withdrawal. Aldicarb could be applied once to the ground for season-long control of certain insect species. Without aldicarb, growers are using alternative chemicals that need to be applied 5 to 6 times as foliar sprays to the potato plants in order to control the same pests. Thus, the potato growers are telling EPA that the loss of aldicarb has actually increased the spraying of chemicals in potato fields. In addition, the potato growers report that the alternative chemicals are performing less well in the control of certain insect species, particularly aphids. These aphids transmit viruses to the potato plants. Aldicarb controlled the aphids very well and the viruses were not a problem. The potato growers are reporting that the viruses have reappeared since the aldicarb withdrawal. The major threat is to the seed potato industry where production of virus-free potato seed is a necessity. Thus, the potato growers, particularly in the Northwest, are reporting that the loss of aldicarb is a serious threat to the viability of the seed potato industry.

The major use of benomyl in the U.S. is for control of diseases in rice. Our data indicate that about 1/3 of benomyl's agricultural use is in rice fields, particularly in Arkansas, Louisiana, Mississippi and Texas. Rice growers face the potential loss of benomyl due to a strict interpretation of the Delaney Clause. Rice growers in Southeastern states have recently commented to EPA on the uses of benomyl. They report that benomyl is the only synthetic fungicide available to control the disease known as rice blast. Epidemics of rice blast occurred in Southeastern states in both 1991 and 1992 with susceptible cultivars incurring yield losses of up to 60%. Estimates of the quantity of benomyl applied in the southern rice crop during those years indicate that 33% of the rice acres were treated with one pound annually, saving rough rice valued at approximately \$85 million for each of 1991 and 1992.

In summary, I think that most analysts would agree with one of the very first sentences in the NAS report on *Pesticides in the Diets of Infants and Children*. "Chemical pest control has contributed to dramatic increases in yields for most major fruit and vegetable crops". In making policy to reduce pesticide use or risks, it's important for policymakers to understand the integral role that chemical pesticides play in the production of food and fiber in the U.S. The uses of pesticides are complicated. The benefits of pesticide use are substantial.



ISBN 0-16-043470-X



90000



9 780160 434709

